SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

Introduction

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | WM Research Collaborative | NWRC North West Research Collaborative

FUNDED BY NIHR | National Institute for Health Research

This study is funded by the NIHR Research for Patient Benefit (RfPB) (ref. PB-PG-0416-20045). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Introduction

SUNRRISE

- **Funders:** NIHR RfPB
- **Sponsor:** University of Birmingham
- **Chief Investigators:**
  - Mr Richard Wilkin (UHB, Queen Elizabeth Hospital); r.wilkin@bham.ac.uk
  - Mr Hamish Clouston (The Christie); hamish.clouston@christie.nhs.uk
- **Coordinating Centre:** The University of Birmingham Clinical Trials Unit (BCTU)

Support and oversight are provided to the CIs by :

- Mr Tom Pinkney (UHB, Queen Elizabeth Hospital); Thomas.Pinkney@uhb.nhs.uk
- Mrs Sarah Duff (MUFT, Wythenshawe Hospital); sarah.duff@mft.nhs.uk

SUNRRISE Trial Office contact details:

E-mail: SUNRRISE@trials.bham.ac.uk
Tel: 0121 414 9012 / 077 8510 2378
Fax: 0121 415 8871

Senior Trial Manager: James Brown
E-mail: j.p.brown.1@bham.ac.uk
Data Manager: Erum Khan
E-mail: e.khan@bham.ac.uk

Address: SUNRRISE Trial Office,
Birmingham Clinical Trials Unit (BCTU)
Public Health Building
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Role of BCTU

- Site set-up
- Trial coordination according to:
  - Good Clinical Practice
  - UK Policy Framework for Health and Social Care Research
  - UoB and BCTU SOPs
- Protocol guidance
- Queries (e.g. patient pathway, eligibility)
- Randomisation via CHaRT (University of Aberdeen)
- Data collection, entry and management
- Receipt and review of SAEs
- Monitoring
- Statistical analysis (health economics analysis undertaken by NWSTC)
- Database creation and maintenance
- Coordination of trial supplies; communicate with Smith & Nephew to initiate supply and request resupply

Site-specific Training objectives

PART 1
- Trial overview (background, rationale, trial design)
- Primary & secondary objectives & outcomes
- Patient eligibility (inclusion & exclusion criteria)
- Trial schema

PART 2
- Participant identification and consent
- Randomisation procedures
- Intervention

PART 3
- Trial activities, paperwork and CRFs including patient discontinuation
- Assessment schedule
- Source data

PART 4
- Safety reporting

PART 5
- Delegation of duties and training
- Authorship policy and Associate PI scheme
- PI oversight
- Compliance, monitoring and audits
- Confidentiality
- Investigator site file
- Archiving

PART 6
- SUNPD supplies
- Other trial supplies

SUNRRISE

Thank you

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

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Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 1

- Trial overview (background, rationale, trial design)
- Primary and secondary objectives and outcomes
- Patient eligibility (inclusion and exclusion criteria)
- Trial schema

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Trial Overview

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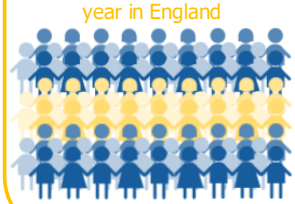
BACKGROUND

30,000 emergency laparotomies per year in England



Up to **25% - 40%** of patients undergoing an emergency laparotomy develop an SSI.

The average cost of an SSI is **£3500**

Trial Overview

SUNRRISE

RATIONALE

SSI is associated with:
- considerable morbidity

- a reduction in quality of life

- increased healthcare costs.

Development of an SSI significantly increases patient hospitalisation, additional nursing care and drug treatment costs.

Trial Overview

SUNRRISE

TRIAL DESIGN
- Pragmatic, international, multi-centre, prospective phase III randomised controlled trial with internal feasibility study
- Collaborative
- Outcome assessor blinded

- **1:1 randomisation:**

Single-use negative pressure dressing (SUNPD)

vs.

Surgeon's Preference

(which may be simple* conventional occlusive dressings, skin glue or no dressing
BUT not another type of negative pressure dressing)

*not silver, honey or iodine, or any other type of negative pressure dressing

Trial Overview

SUNRRISE

STATISTICS

- Minimisation variables;
  i) Degree of contamination; clean, clean-contaminated, contaminated, dirty

  ii) Presence of stoma; Yes / No (*Also collecting data on whether pre-existing or newly formed)*

  (iii) Centre

- **Sample size:** 840
  - Based on a baseline SSI rate of 25%
  - Relative reduction of 40% (to 15% SSI rate)
  - 80% power, 5% Type 1 error
  - 250 patients per arm
  - 20% attrition rate
    → Originally sample size was 630 at 80% power but this was increased due to the inclusion of the Australian arm

Trial Overview

SUNRRISE

TRIAL OBJECTIVES

Primary objective:
To determine if the use of a SUNPD in adult patients undergoing emergency laparotomy reduces SSI at 30 days compared to surgeon's preference of dressing *(which may be conventional occlusive dressings, skin glue or no dressing but not another type of negative pressure dressing).*

Secondary objectives:
To determine if use of a SUNPD:

- Reduces length of hospital stay after surgery
- Reduces the rate of wound complications
- Reduces wound complication related hospital re-admission rates
- Improves health-related quality of life
- Is safe in this population
- Is acceptable to patients and healthcare professionals
- Is cost-effective compared to the use of the surgeon's preference of dressing

Trial Overview

SUNRRISE

TRIAL OUTCOMES

Primary outcome:

SSI within 30 days of surgery, as defined by CDC criteria.

Wound assessment will be conducted on:

- Day 7 post-operation or on discharge (whichever is sooner) by a trained wound assessor
- Day 30 day post-operation, by a blinded and trained wound assessor
- The intervening period will be covered by a structured patient diary

The following CDC definition will be used to identify an SSI:

The infection must occur within 30-days of the index operation

AND

The patient must have at least one of the following:

- Purulent drainage from the wound
- Organisms are detected from a wound swab
- Wound opened spontaneously or by a clinician AND, at the surgical wound, the patient has at least one of:
  - pain or tenderness
  - localised swelling
  - redness
  - Heat
  - systemic fever (>38^{0}C)
- Diagnosis of SSI by a clinician or on imaging

Online training module for diagnosis of SSI

https://bctu-redcap.bham.ac.uk/surveys/?s=DFPM7YMKRJ

Trial Overview

SUNRRISE

TRIAL OUTCOMES

Secondary outcomes:

- Length of hospital stay after surgery
- Wound complications within 30 days post-surgery graded by Clavien-Dindo scale
- Hospital re-admission for wound related complications within 30 days.
  - These will include SSIs, wound breakdown/ dehiscence, seromas and wound related pain
- Health-related Quality of Life assessed using:
  - SF-12 at baseline, day 7 and day 30
  - EQ-5D-5L at baseline, day 7, day 14, day 21 and day 30
  - Pain at the site of the primary laparotomy at day 7 and day 30
  - Patient dairy with daily questions set from discharge to day 30
- Cost-effectiveness assessed using a patient diary for patient reported healthcare resource usage
- Serious adverse events up to 30 days
- Health professional's acceptability of use of SUNPD (via a survey of users) UK ONLY
- Patient acceptability of use of their dressing at day 7

Patient Eligibility

SUNRRISE

INCLUSION CRITERIA

- ☑ **Patients undergoing emergency (non-elective) laparotomy**
- ☑ Procedures with an incision of at least 5cm
- ☑ Operations where the skin is closed primarily
- ☑ Patients aged at least 16 years
- ☑ Patients able to provide written informed consent, or consultee provide assent (declaration) if a patient temporarily lacks capacity
- ☑ Patients willing and able to undergo follow-up at 30 days post-op

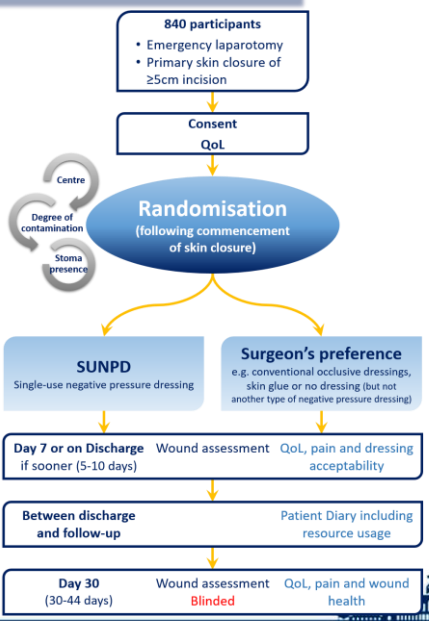
EXCLUSION CRITERIA

- ☒ Abdominal surgery within the preceding three months of randomisation
- ☒ Expected return to theatre for reopening of laparotomy wound within 30 days

Prior to randomisation, eligibility must be confirmed by a medically qualified doctor with access to and a full understanding of the potential participant's medical history who has been appropriately delegated the duty on SUNRRISE Site Signature and Delegation Log.

Trial Schema: Overview

SUNRRISE



Trial Schema: Detailed – Baseline

SUNRRISE

Summary of trial events and activities at baseline

SITE ACTIVITY	EVENT / TIME POINT	PATIENT ACTIVITY
	Patient admitted	
	Decision to operate • Emergency laparotomy • Primary skin closure of ≥5cm incision	
Given PIS Contact Research Team Eligibility confirmed and consent taken		Consider participation Give consent
Give QoL (EQ-5D & SF-12) to patient Begin to complete Randomisation form		Complete QoL (EQ-5D & SF-12)
	Taken to theatre	
Add *actual* operative details to Randomisation form RANDOMISE	Skin closure commenced	
Apply SUNPD or Surgeon's preference of dressing (as allocated)	End of operation	
Complete In-Theatre form, ideally by operating surgeon Add trial number to consent and QoL	Immediately post-op	

Study-specific Training - PART 1 v1.0 (01-Oct-2020) Slide 11

Trial Schema: Detailed – Follow-up

SUNRRISE

Summary of trial events, time points and activities associated with FU

SITE ACTIVITY	EVENT / TIME POINT	PATIENT ACTIVITY
SUNPD removed (if present) Complete Day 7 CRF and assess the wound Add TNo to Patient diary, cross out unnecessary pages and give to patient Arrange Day 30 follow-up	Day 5-10 post-op (or at discharged if sooner)	Comment on wound pain and dressing acceptability Complete QoL
Contact patient on Day 14 and 21 to ensure Patient Diary (including QoL) are being completed	Between discharge and follow-up	Complete Patient Diary: • Daily questions • EQ-5D on Day 14 and 21
BLINDED assessment of wound Complete Day 30 CRF Collect Patient Diary Ensure Day 30 QoL have been completed *If ongoing SSI*, add TNo to Patient diary (Continuing Involvement) and give to patient	Day 30-44 post-op	Before review, complete Bluebelle wound healing questionnaire (ideally at home) Complete QoL Comment on wound pain
Contact patient regularly to ensure Patient Diary being completed and to arrange return	If ongoing SSI After Day 30 assessment	Complete Patient Diary: • Daily questions
Complete Return to Theatre form	Any time between the operation and Day 30	Returns to theatre
Complete SAE form within 24 hours of becoming aware and send to BCTU straightaway		Experiences an SAE (e.g. prolonged hospital stay or re-admission)

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Thank you

Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

SUNRRISE

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Site-specific Training Presentation

PART 2

- Participant identification and Consent
- Randomisation procedures
- Intervention

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Trial Schema: Detailed – Baseline

SUNRRISE

Summary of trial events and activities at baseline

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Give QoL (EQ-5D & SF-12) to patient Begin to complete Randomisation form		Complete QoL (EQ-5D & SF-12)
	Taken to theatre	
Add *actual* operative details to Randomisation form RANDOMISE	Skin closure commenced	
Apply SUNPD or Surgeon's preference of dressing (as allocated)	End of operation	
Complete In-Theatre form, ideally by operating surgeon Add trial number to consent and QoL	Immediately post-op	

Patient Identification

- Potential participants will likely be identified by either a consultant or trainee surgeon once the decision to take them to theatre has been made
- Patients will be approached by a member of the research team - this member of the research team may be either a member of the clinical team or a research nurse
  - Ensure patients understand the importance of undergoing a review at day 30 when they are considering taking part
- Prior to randomisation:
  1. **Eligibility** for enrolment in SUNRRISE must be confirmed by a medically qualified doctor evidenced by signature on the randomisation form
  2. **Written informed consent** for participation in SUNRRISE must always be obtained by a doctor or nurse

Ensure all staff involved in the trial (directly and indirectly) are aware that before a patient can be randomised, a SUNRRISE-specific consent form must be completed by the patient (or a declaration form by the personal consultee/consent from by legal representative), especially if they are new to research and/or the trial

Screening and screening logs

- Logs to be kept in accordance with the CONSORT guidance and GCP
- It is suggested that a research team member reviews the theatre logbook on a weekly/monthly basis to identify patients who have undergone an emergency laparotomy but were not randomised into the trial

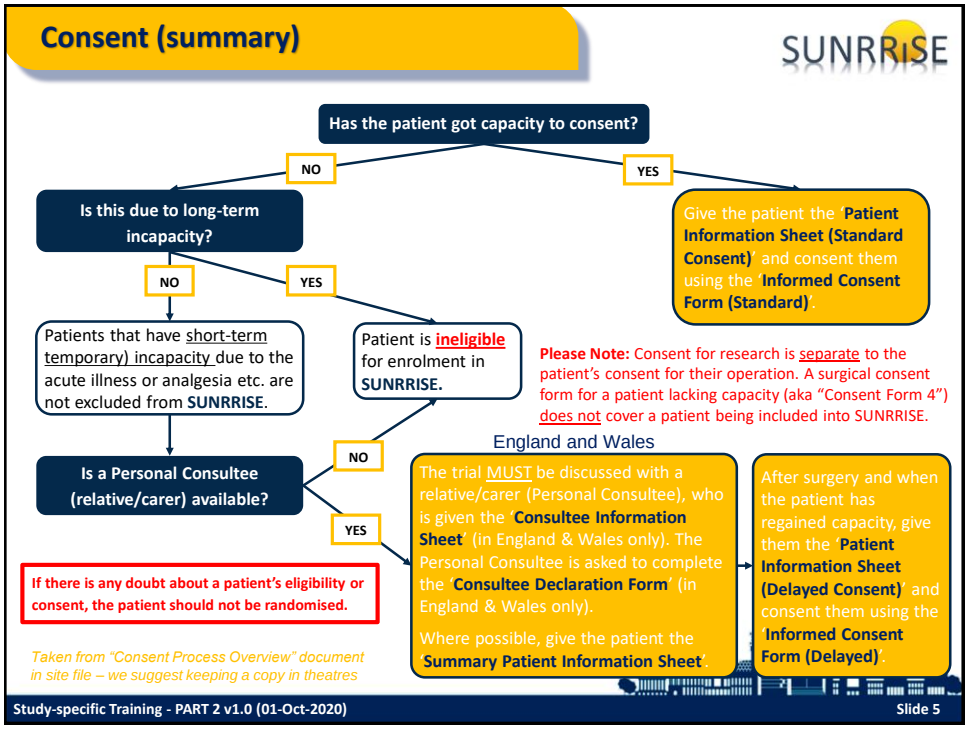
How will this be done at your site?

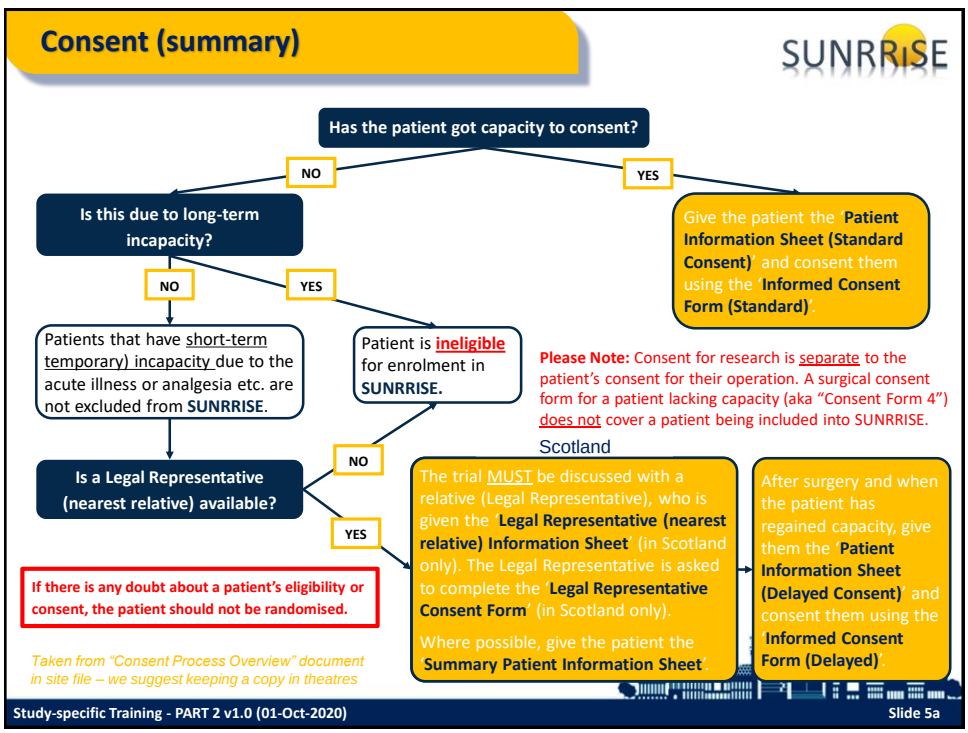
Who will do it?

- The reasons for non-randomisation will be recorded on the screening log
  - This information may be found by reviewing patient records or liaising with the clinical team
  -

REASONS PATIENT NOT ELIGIBLE/NOT RANDOMISED *Please use these reason codes where possible; if patient did not enter trial for any other reason please state/describe above.*							
A.	Procedure not an emergency laparotomy	B.	Patient aged less than 16 years old	C.	Incision of less than 5cm	D.	Skin not primarily closed
E.	Due to long-term incapacity, patient unable to provide informed consent	F.	Personal Consultee/legal Representative unavailable	G.	Personal Consultee/legal Representative reported objection	H.	Patient unwilling or unable to attend follow-up at 30 days post-op
I.	Expected return to theatre for reopening of laparotomy wound within 30 days	J.	Abdominal surgery within the preceding three months of randomisation	K.	Patient declined (please **also state reason** or confirm patient did not wish to provide one)	L.	No one GCP trained and/or assigned duty available to take consent and/or confirm eligibility
M.	SUNPD dressing unavailable	N.	No trained surgeon to place dressing	O.	Patient missed i.e. not identified pre-op	P.	Operation did not go ahead

  - If patients decline, please included they reason given (or confirm that they did not wish to provide one)


Consent (summary)
SUNRRISE
Has the patient got capacity to consent?
NO
YES
Is this due to long-term incapacity?
Give the patient the 'Patient Information Sheet (Standard Consent)' and consent them using the 'Informed Consent Form (Standard)'.
NO
YES
Patients that have short-term temporary) incapacity due to the acute illness or analgesia etc. are not excluded from SUNRRISE.
Patient is ineligible for enrolment in SUNRRISE.
Please Note: Consent for research is separate to the patient's consent for their operation. A surgical consent form for a patient lacking capacity (aka "Consent Form 4") does not cover a patient being included into SUNRRISE.
England and Wales
Is a Personal Consultee (relative/carer) available?
NO
YES
The trial MUST be discussed with a relative/carer (Personal Consultee), who is given the 'Consultee Information Sheet' (in England & Wales only). The Personal Consultee is asked to complete the 'Consultee Declaration Form' (in England & Wales only).
Where possible, give the patient the 'Summary Patient Information Sheet'.
After surgery and when the patient has regained capacity, give them the 'Patient Information Sheet (Delayed Consent)' and consent them using the 'Informed Consent Form (Delayed)'.
If there is any doubt about a patient's eligibility or consent, the patient should not be randomised.
Taken from "Consent Process Overview" document in site file – we suggest keeping a copy in theatres
Study-specific Training - PART 2 v1.0 (01-Oct-2020)
Slide 5


Consent (summary)
SUNRRISE
Has the patient got capacity to consent?
NO
YES
Is this due to long-term incapacity?
Give the patient the 'Patient Information Sheet (Standard Consent)' and consent them using the 'Informed Consent Form (Standard)'.
NO
YES
Patients that have short-term temporary) incapacity due to the acute illness or analgesia etc. are not excluded from SUNRRISE.
Patient is ineligible for enrolment in SUNRRISE.
Please Note: Consent for research is separate to the patient's consent for their operation. A surgical consent form for a patient lacking capacity (aka "Consent Form 4") does not cover a patient being included into SUNRRISE.
Scotland
Is a Legal Representative (nearest relative) available?
NO
YES
The trial MUST be discussed with a relative (Legal Representative), who is given the 'Legal Representative (nearest relative) Information Sheet' (in Scotland only). The Legal Representative is asked to complete the 'Legal Representative Consent Form' (in Scotland only).
Where possible, give the patient the 'Summary Patient Information Sheet'.
After surgery and when the patient has regained capacity, give them the 'Patient Information Sheet (Delayed Consent)' and consent them using the 'Informed Consent Form (Delayed)'.
If there is any doubt about a patient's eligibility or consent, the patient should not be randomised.
Taken from "Consent Process Overview" document in site file – we suggest keeping a copy in theatres
Study-specific Training - PART 2 v1.0 (01-Oct-2020)
Slide 5a

Consent

SUNRRISE

Consent should only be taken after that person is informed of nature, significance, implications and risks of trial

- Written, informed consent from a patient (or assent/declaration from a patient's personal consultee) **must** be obtained for all patients:
  - Prior to Randomisation
  - By a suitably trained, delegated investigator who is listed on the delegation log
    - *the investigator must have been trained and authorised by the PI before undertaking any study-specific activities and procedures*
  - After Patient (or consultee) Information Sheet and full verbal explanation of the trial given

If necessary, translators should be provided for patients unable to understand English

Consent

SUNRRISE

Patients with capacity to give consent…

- Process for approaching the participant and taking consent occur in the usual manner
  - Patient is given the Patient Information Sheet (Standard) and the opportunity to discuss the trial with a member of the research team
  - Patient completes Informed Consent Form (Standard) and the form is countersigned by the person taking consent

Current approved versions:
Patient Information Sheet (Standard Consent) = **v3.0 (05-Aug-2020)**
Informed Consent Form (Standard) = **v3.0 (05-Aug-2020)**

Patients lacking capacity *long-term*…

- If a patient's lack of capacity to consent is not temporary, they cannot be entered into the study

i.e. ineligible for enrolment in the trial

Consent

SUNRRISE

Patients *temporarily* lacking capacity to give consent…

- In the emergency setting, patients may not have capacity to provide informed consent as a result of the condition for which they require surgery
- **IN ENGLAND & WALES** such patients can still be enrolled if they have a **Personal Consultee (PC)** present
  Personal Consultee: a person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity

If a PC is unavailable, the patient cannot be entered into the study

- Process for approach and consent:
  - Patient is given the Summary Patient Information Sheet (where possible)
  - PC is given Consultee Information Sheet and the opportunity to discuss the trial with a member of the research team
  - PC then provides assent using the Consultee Declaration Form and the form is countersigned by the person taking assent
  - Once the patient regains capacity, consent is to be sought using the Patient Information Sheet (Delayed) & Informed Consent Form (Delayed)

Current approved versions:
Consultee Information Sheet = **v3.0 (05-Aug-2020)**
Consultee Declaration Form = **v3.0 (05-Aug-2020)**

Consent

SUNRRISE

Patients *temporarily* lacking capacity to give consent…

- In the emergency setting, patients may not have capacity to provide informed consent as a result of the condition for which they require surgery
- **IN SCOTLAND** such patients can still be enrolled if they have a **Legal Representative (nearest relative) (LR)** present
  Adults with Incapacity (Scotland) Act uses the hierarchy of relationships *- in decreasing order of closeness: Spouse; Child; Father/ Mother; Brother/Sister; Grandparent; Grandchild; Uncle/Aunt; Nephew/Niece*

If a LR is unavailable, the patient cannot be entered into the study

- Process for approach and consent:
  - Patient is given the Summary Patient Information Sheet (where possible)
  - LR is given Legal Representative Information Sheet and the opportunity to discuss the trial with a member of the research team
  - PC then provides consent using the Legal Representative Consnet Form and the form is countersigned by the person taking consent
  - Once the patient regains capacity, consent is to be sought using the Patient Information Sheet (Delayed) & Informed Consent Form (Delayed)

Current approved versions:
LR Information Sheet = **v2.0 (05-Aug-2020)**
LR Consent Form = **v2.0 (05-Aug-2020)**

Consent

SUNRRISE

General points on consent…

- Investigators approaching and consenting participants must ensure they adequately explain:
  - That consent is being sought for inclusion in a randomised controlled trial
  - The trial is comparing different dressings aiming to reduce SSI rates
  - That the intervention they receive will be allocated at random
  - That participation is voluntary and the participant is free to refuse to take part and may withdraw from the trial at any time, without impact on their clinical care
  - That one additional follow-up review at 30 days post-surgery is required
  - That on discharge from hospital, they will be provided with a diary to fill out detailing interactions with healthcare professionals and an assessment of their health status
  - That the participant will be contacted at weekly intervals via telephone or text to remind them to fill out the Patient Diary
- Clinicians/nurses can introduce the trial if delegated this task (i.e. "inform patient of trial")
- Clinicians/nurses can obtain consent (or assent/declaration) - they must have been delegated this task and hold a current GCP certificate
  - There is no minimum required time between patient approach and consent

Consent

SUNRRISE

General points on consent…

- Consent/Declaration forms should be check for common errors;
  - boxes not initialled, boxes missing, dates incorrect, footer missing
- What to do with the Consent/Declaration forms?
  - Original filed in ISF
  - Copy given to patient
  - Copy added to the patient's medical notes
  - Copy sent to BCTU
- Details must be documented in the patient's medical notes;
  - trial name, dates, summary of discussion, versions of documents used
- **Consent is an ongoing process** - a patient's willingness to continue should be ensured and documented in the medical notes at each FU assessment

CHECK OUT THE GRANULE COURSE
Available online free through the NIHR Learn (same system through which GCP training is accessed); https://learn.nihr.ac.uk/

Patient Eligibility

SUNRRISE

INCLUSION CRITERIA

- ☑ **Patients undergoing emergency (non-elective) laparotomy**
- ☑ Procedures with an incision of at least 5cm
- ☑ Operations where the skin is closed primarily
- ☑ Patients aged at least 16 years
- ☑ Patients able to provide written informed consent, or consultee provide assent (declaration) if a patient temporarily lacks capacity
- ☑ Patients willing and able to undergo follow-up at 30 days post-op

EXCLUSION CRITERIA

- ☒ Abdominal surgery within the preceding three months of randomisation
- ☒ Expected return to theatre for reopening of laparotomy wound within 30 days

Prior to randomisation, eligibility must be confirmed by a medically qualified doctor with access to and a full understanding of the potential participant's medical history who has been appropriately delegated the duty on SUNRRISE Site Signature and Delegation Log.

Randomisation Procedure

SUNRRISE

At commencement of skin closure…

Completed documents:
- Trial Consent (or Declaration) Form
- Baseline QoL Booklet
- Randomisation Form

24 hr automated telephone service
0800 2802 307
OR
24 hr online service
https://w3.abdn.ac.uk/hsru/SUNRRISE

Take care when entering responses for the degree of contamination and stoma presence
These are minimisation variables so if entered incorrectly it could introduce imbalances between arms – if the values entered are not accurate/do not match the Randomisation Form notify BCTU ASAP.

Enter information

Trial Number issued
_ _ _ _ _
AND
Allocation given
SUNPD
or
Surgeon's preference

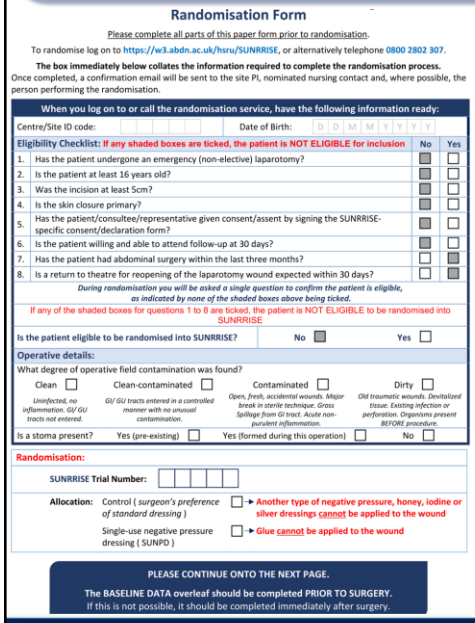
Write these on the form

Confirmation of SUNRRISE Randomisation e-mailed to PI and nominated site contacts
Participant details only – allocation not included to avoid unnecessary unblinding

"Randomisation Quick Reference Guide" is provided for display in theatre and detailed instructions for the telephone service can be found in the site file (section 10)

Randomisation Procedure

SUNRRISE



Randomisation Form

Please complete all parts of this paper form prior to randomisation.

To randomise log on to https://w3.abdn.ac.uk/hsru/SUNRRISE, or alternatively telephone 0800 2802 307.

The box immediately below collates the information required to complete the randomisation process.

Once completed, a confirmation email will be sent to the site PI, nominated nursing contact and, where possible, the person performing the randomisation.

When you log on to or call the randomisation service, have the following information ready:

Centre/Site ID code: Date of Birth: D D M M Y Y Y Y

Eligibility Checklist: If any shaded boxes are ticked, the patient is NOT ELIGIBLE for inclusion		No	Yes
1.	Has the patient undergone an emergency (non-elective) laparotomy?	■	☐
2.	Is the patient at least 16 years old?	■	☐
3.	Was the incision at least 5cm?	■	☐
4.	Is the skin closure primary?	■	☐
5.	Has the patient/consultee/representative given consent/assent by signing the SUNRRISE-specific consent/declaration form?	■	☐
6.	Is the patient willing and able to attend follow-up at 30 days?	■	☐
7.	Has the patient had abdominal surgery within the last three months?	☐	■
8.	Is a return to theatre for reopening of the laparotomy wound expected within 30 days?	☐	■

During randomisation you will be asked a single question to confirm the patient is eligible, as indicated by none of the shaded boxes above being ticked.

If any of the shaded boxes for questions 1 to 8 are ticked, the patient is NOT ELIGIBLE to be randomised into SUNRRISE

Is the patient eligible to be randomised into SUNRRISE? No ■ Yes ☐

Operative details:

What degree of operative field contamination was found?

Clean ☐ *Uninfected, no inflammation. GI/ GU tracts not entered.*

Clean-contaminated ☐ *GI/ GU tracts entered in a controlled manner with no unusual contamination.*

Contaminated ☐ *Open, fresh, accidental wounds. Major break in sterile technique. Gross Spillage from GI tract. Acute non-purulent inflammation.*

Dirty ☐ *Old traumatic wounds. Devitalized tissue. Existing infection or perforation. Organisms present BEFORE procedure.*

Is a stoma present? Yes (pre-existing) ☐ Yes (formed during this operation) ☐ No ☐

Randomisation:

SUNRRISE Trial Number: ☐☐☐☐☐

Allocation: Control (*surgeon's preference of standard dressing*) ☐ → **Another type of negative pressure, honey, iodine or silver dressings cannot be applied to the wound**

Single-use negative pressure dressing (SUNPD) ☐ → **Glue cannot be applied to the wound**

PLEASE CONTINUE ONTO THE NEXT PAGE.

The BASELINE DATA overleaf should be completed PRIOR TO SURGERY.
If this is not possible, it should be completed immediately after surgery.

RANDOMISATION FORM

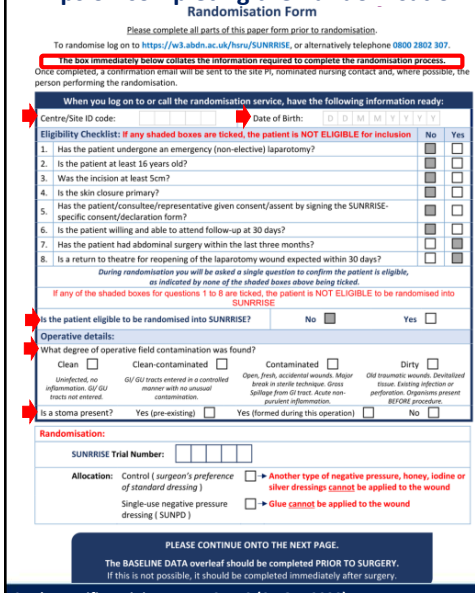
- **Data required to randomise** – cannot randomise if missing/unknown:
  - Patient DOB
  - Eligibility details
  - Operative details = minimisation variables
    - Take special care when entering these responses – they must be accurate
- Most parts/questions can be answered before the operation
- Some data will not be known/confirmed until the patient is in theatre

Page 1 = information that is required to complete the randomisation process

Randomisation Procedure

SUNRRISE

Tips on completing the Randomisation Form…



Randomisation Form

Please complete all parts of this paper form prior to randomisation.

To randomise log on to https://w3.abdn.ac.uk/hsru/SUNRRISE, or alternatively telephone 0800 2802 307.

The box immediately below collates the information required to complete the randomisation process.

Once completed, a confirmation email will be sent to the site PI, nominated nursing contact and, where possible, the person performing the randomisation.

When you log on to or call the randomisation service, have the following information ready:

Centre/Site ID code: Date of Birth: D D M M Y Y Y Y

Eligibility Checklist: If any shaded boxes are ticked, the patient is NOT ELIGIBLE for inclusion		No	Yes
1.	Has the patient undergone an emergency (non-elective) laparotomy?	■	☐
2.	Is the patient at least 16 years old?	■	☐
3.	Was the incision at least 5cm?	■	☐
4.	Is the skin closure primary?	■	☐
5.	Has the patient/consultee/representative given consent/assent by signing the SUNRRISE-specific consent/declaration form?	■	☐
6.	Is the patient willing and able to attend follow-up at 30 days?	■	☐
7.	Has the patient had abdominal surgery within the last three months?	☐	■
8.	Is a return to theatre for reopening of the laparotomy wound expected within 30 days?	☐	■

During randomisation you will be asked a single question to confirm the patient is eligible, as indicated by none of the shaded boxes above being ticked.

If any of the shaded boxes for questions 1 to 8 are ticked, the patient is NOT ELIGIBLE to be randomised into SUNRRISE

Is the patient eligible to be randomised into SUNRRISE? No ■ Yes ☐

Operative details:

What degree of operative field contamination was found?

Clean ☐ *Uninfected, no inflammation. GI/ GU tracts not entered.*

Clean-contaminated ☐ *GI/ GU tracts entered in a controlled manner with no unusual contamination.*

Contaminated ☐ *Open, fresh, accidental wounds. Major break in sterile technique. Gross Spillage from GI tract. Acute non-purulent inflammation.*

Dirty ☐ *Old traumatic wounds. Devitalized tissue. Existing infection or perforation. Organisms present BEFORE procedure.*

Is a stoma present? Yes (pre-existing) ☐ Yes (formed during this operation) ☐ No ☐

Randomisation:

SUNRRISE Trial Number: ☐☐☐☐☐

Allocation: Control (*surgeon's preference of standard dressing*) ☐ → **Another type of negative pressure, honey, iodine or silver dressings cannot be applied to the wound**

Single-use negative pressure dressing (SUNPD) ☐ → **Glue cannot be applied to the wound**

PLEASE CONTINUE ONTO THE NEXT PAGE.

The BASELINE DATA overleaf should be completed PRIOR TO SURGERY.
If this is not possible, it should be completed immediately after surgery.

- **Data required to randomise** – cannot randomise if missing/unknown:
  - Patient DOB
  - Eligibility details
  - Operative details = minimisation variables
    - Take special care when entering these responses – they must be accurate
- Most parts/questions can be answered before the operation
- Some data will not be known/confirmed until the patient is in theatre

Page 1 = information that is required to complete the randomisation process

Randomisation Procedure

SUNRRISE

Identifying Details			
Patient forename(s):		Patient sex:	Male ☐ Female ☐
Patient surname:		NHS/CHI No:	

Confirmation of Eligibility	
SUNRRISE eligibility must be confirmed by a medically trained individual (Doctor). By signing this form, the named clinician confirms that the information provided on this document is true and that this patient fulfils all necessary criteria for inclusion into the SUNRRISE trial.	
Name of medically qualified doctor confirming eligibility for entry into the trial:	
Signature of medically qualified doctor confirming eligibility for entry into the trial:	
Date eligibility was confirmed:	D D M M Y Y Y Y

Quality of Life		
Has the patient completed the Quality of Life questionnaires (SF-12 and EQ-5D), which should be completed prior to surgery?	No ☐	Yes ☐
↳ If **No**, please explain why not? _____		

Baseline Data			
BMI: ☐☐.☐ *If BMI is not available, please provide:*	Height (in cm): ☐☐☐	Weight (in kg): ☐☐☐	
Serum albumin level (in g/L): ☐☐	*(Expected ranged: 20-50 Max range: 5-80)*		
Does the patient have known diabetes?	No ☐	Yes ☐	
↳ If **Yes**, how is it managed: (tick all that apply)	Diet-controlled ☐	Tablets ☐	Insulin ☐
What is the patient's smoking status? *(E-cigarette use is not considered smoking)*	Never smoked ☐	Current smoker *(or stopped smoking ≤6 weeks ago)* ☐	Ex-smoker *(stopped smoking >6 weeks ago)* ☐
Is the patient on any immunosuppressive therapy? *(oral or inhaled immunosuppressive medication including steroids, or immunosuppressed due to pre-existing medical condition)*	No ☐	Yes ☐	
Is the patient clinically jaundiced? *(or serum bilirubin >50 µmol/L)*	No ☐	Yes ☐	
Does the patient have an active malignancy? *(does not have to be the condition being operated on)*	No ☐	Yes ☐	

Form completed by:			
Full Name: (PRINT NAME)		**Position:**	
Signature:		**Date:**	D D M M Y Y Y Y

RANDOMISATION FORM

- Page 2 = patient identifiers, baseline data and eligibility confirmation

Please note – Patient identifiers are only collected on the randomisation and consent forms. Other CRFs and correspondence use only Trial Number and patient initials

Intervention

SUNRRISE

PICO™ 7 is the single-use negative pressure dressing (SUNPD)

- Kits include; 2x dressings, 8x secondary retention/fixation strips, 1x pump, 2x AA batteries, 1x belt clip, 1x instructions
- Available in 3 sizes;

Size (cm)	20 x 10	30 x 10	40 x 10
Pad size (cm)	15 x 5.6	25 x 5.6	35 x 5.6

- **1st dressing**
  - Applied to wound at the end of operation
  - Applied by research team member trained in application of SUNPD and delegated the duty
- **2nd dressing**
  - To be kept with patient in case dressing change is required
  - If applied, *ideally* by research team member trained of in application of SUNPD

SUNPD supplies… Contact the Trial Office
surrise@trials.bham.ac.uk

Intervention

SUNRRISE

PICO™ 7 is the single-use negative pressure dressing (SUNPD)

Training on the application and use of PICO 7 is provided by **Smith & Nephew** initially prior to site opening, and by the PI (or delegated individual)

Overview (taken form Smith & Nephew PICO 7 Quick Reference Guide (PCEE2-14182-0818)…

Application guide

1. Clean and prepare wound according to local protocol.

Dress

2. Peel off the first release handle and place the dressing centrally over the wound. The port should be uppermost from the wound.
3. Remove the other two handles and smooth the dressing around the wound to prevent creasing.

Press

4. Insert the batteries into the device.
5. Join the device to the dressing by twisting together the tubing connectors.

6. Press the orange button to start the application of negative pressure. The green light will start to flash (indicates system working OK).

Go

7. Apply the fixation strips to each of the four sides of the dressing.
8. The device has a 7 day life and the dressing may be left in place for up to 7 days depending on the level of exudate.

Dressing change indicator

A Dressing properly positioned and is acceptable to be left in place

B Dressing requires change - port may block with fluid

C Dressing requires change - absorbent area is full

Intervention

SUNRRISE

PICO™ 7 is the single-use negative pressure dressing (SUNPD)

Considerations when applying dressings…

- **If TAP/rectus sheath catheters are to be placed, they should be place laterally enough so they do not disrupt the seal of the dressing**
- **If wound is longer than 35cm (pad size of 40 cm dressings)…**
  - Use standard occlusive dressing for remainder of wound
  - Apply occlusive dressing first to the *lower* risk end
  - Then PICO to be placed at *higher* risk end
- **Stomas – not to be applied over stoma openings and ensure sufficient space between the stoma and wound to accommodate the adhesive rim of the dressing**
  - Fixation/secondary retention strips and adhesive rim of the dressing may be cut/trimmed to a degree BUT it must still be possible to obtain an airtight seal
  - The dressing pad should not be cut/trimmed
  - When there will be overlap with flange/wafer, applied the PICO dressing first
  - Care should be taken when changing stoma flange/wafers as they can pull at the dressing and break the seal

If it is anticipated that a PICO 7 dressing cannot be applied, the patient should not be randomised.

Intervention

PICO™ 7 is the single-use negative pressure dressing (SUNPD)

- **Dressing to remain in place until wound review at day 7 or discharge**
  - Patients are **not** to be discharged with the SUNPD dressing
- If second dressing is unused at the end of treatment, retain with other dressing stocks
  - Can be used as additional dressings if more than 2 are needed for other SUNRRISE participants
  - Unused stock must be returned at the end of the trial
- Urgent clinical queries… contact members of the SUNRRISE TMG directly via the **"SUNRRISE Questions"** WhatsApp group;
  - access using the QR code or link given here, alternatively contact the CI, Richard Wilkin, on 07956147189 to add you to the group

https://chat.whatsapp.com/HY6np2gJPCD8dp3X4FhuFY

The aim of the group is to allow researchers at site to communicate directly with the clinical members of the Trial Management Group about clinical queries and issues within the trial that require more immediate responses.

General queries should still be directed to the SUNRRISE Trial Office.

Study-specific Training - PART 2 v1.0 (01-Oct-2020) Slide 20

Follow Up

Time point	Activity	CRF
Immediately post-op		In-theatre Form

- **The allocation should not be recorded in the operative note/patient records**
  - State that the patient is participating in the SUNRRISE Trial and the dressing used was either SUNPD or surgeon's preference – labels/stickers are provided
- It may not be possible to prevent any mention in the patient's medical e.g. by ward staff during the patient's admission.
  - The first wound review at day 7 (or discharge if sooner) is not blinded and so is not impacted
  - The second wound review at day 30 is blinded so measures must be take to ensure the assessor is blind to the allocation – the CRF for that assessment asked the assessor to confirm they are blind.

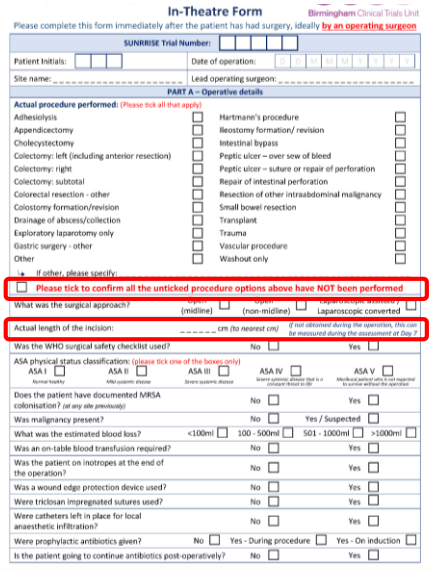
Remember to send out the GP letter

Study-specific Training - PART 2 v1.0 (01-Oct-2020) Slide 21

Follow Up

SUNRRISE

Tips on completing the In-theatre Form…


In-Theatre Form

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

SUNRRISE Trial Number:

Patient Initials: Date of operation:

Site name: Lead operating surgeon:

PART A – Operative details

Actual procedure performed: (Please tick all that apply)

Adhesiolysis; Appendicectomy; Cholecystectomy; Colectomy: left (including anterior resection); Colectomy: right; Colectomy: subtotal; Colorectal resection - other; Colostomy formation/revision; Drainage of abscess/collection; Exploratory laparotomy only; Gastric surgery - other; Other; Hartmann's procedure; Ileostomy formation/ revision; Intestinal bypass; Peptic ulcer – over sew of bleed; Peptic ulcer – suture or repair of perforation; Repair of intestinal perforation; Resection of other intraabdominal malignancy; Small bowel resection; Transplant; Trauma; Vascular procedure; Washout only

If other, please specify:

Please tick to confirm all the unticked procedure options above have NOT been performed

What was the surgical approach? Open (midline); Open (non-midline); Open/Converted to Laparoscopic converted

Actual length of the incision: _____ cm (to nearest cm) (If not obtained during the operation, this can be measured during the assessment at Day 7)

Was the WHO surgical safety checklist used? No; Yes

ASA physical status classification: (please tick one of the boxes only)

ASA I Normal healthy; ASA II Mild systemic disease; ASA III Severe systemic disease; ASA IV Severe systemic disease that is a constant threat to life; ASA V Moribund patient who is not expected to survive without the operation

Does the patient have documented MRSA colonisation? (at any site previously) No; Yes

Was malignancy present? No; Yes / Suspected

What was the estimated blood loss? <100ml; 100 - 500ml; 501 - 1000ml; >1000ml

Was an on-table blood transfusion required? No; Yes

Was the patient on inotropes at the end of the operation? No; Yes

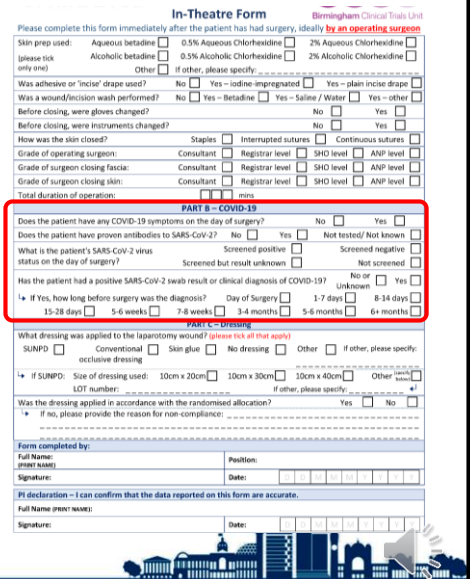
Was a wound edge protection device used? No; Yes

Were triclosan impregnated sutures used? No; Yes

Were catheters left in place for local anaesthetic infiltration? No; Yes

Were prophylactic antibiotics given? No; Yes - During procedure; Yes - On induction

Is the patient going to continue antibiotics post-operatively? No; Yes


In-Theatre Form

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

Skin prep used: Aqueous betadine; 0.5% Aqueous Chlorhexidine; 2% Aqueous Chlorhexidine; Alcoholic betadine; 0.5% Alcoholic Chlorhexidine; 2% Alcoholic Chlorhexidine; Other (please tick only one)

If other, please specify:

Was adhesive or 'incise' drape used? No; Yes – iodine-impregnated; Yes – plain incise drape

Was a wound/incision wash performed? No; Yes – Betadine; Yes – Saline / Water; Yes – other

Before closing, were gloves changed? No; Yes

Before closing, were instruments changed? No; Yes

How was the skin closed? Staples; Interrupted sutures; Continuous sutures

Grade of operating surgeon: Consultant; Registrar level; SHO level; ANP level

Grade of surgeon closing fascia: Consultant; Registrar level; SHO level; ANP level

Grade of surgeon closing skin: Consultant; Registrar level; SHO level; ANP level

Total duration of operation: mins

PART B – COVID-19

Does the patient have any COVID-19 symptoms on the day of surgery? No; Yes

Does the patient have proven antibodies to SARS-CoV-2? No; Yes; Not tested/ Not known

What is the patient's SARS-CoV-2 virus status on the day of surgery? Screened positive; Screened negative; Screened but result unknown; Not screened

Has the patient had a positive SARS-CoV-2 swab result or clinical diagnosis of COVID-19? No or Unknown; Yes

If Yes, how long before surgery was the diagnosis? Day of Surgery; 1-7 days; 8-14 days; 15-28 days; 5-6 weeks; 7-8 weeks; 3-4 months; 5-6 months; 6+ months

PART C – Dressing

What dressing was applied to the laparotomy wound? (please tick all that apply)

SUNPD; Conventional occlusive dressing; Skin glue; No dressing; Other; If other, please specify:

If SUNPD: Size of dressing used: 10cm x 20cm; 10cm x 30cm; 10cm x 40cm; Other (specify below)

LOT number: If other, please specify:

Was the dressing applied in accordance with the randomised allocation? Yes; No

If no, please provide the reason for non-compliance:

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date:

PI declaration – I can confirm that the data reported on this form are accurate.

Full Name (PRINT NAME):

Signature: Date:

SUNRRISE

Thank you

Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 3

- Trial activities, paperwork and CRFs
- Assessment schedule

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | WM Research Collaborative | NWRC North West Research Collaborative

FUNDED BY NIHR | National Institute for Health Research

This study is funded by the NIHR Research for Patient Benefit (RfPB) (ref. PB-PG-0416-20045). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Health-related Quality of Life (summary)

SUNRRISE

What	When	How	To note…
EQ-5D & SF-12	**Post-consent & Pre-op**	**QoL Booklet**	• If not complete pre-op, do not complete post-op
EQ-5D & SF-12	**Day 7** (-2/+3)	**QoL Booklet**◊ or **Patient Diary**	
Daily questions	**Post-discharge to Day 30***	**Patient Diary**	* Day 30 assessment - may be completed at 30-44 days
EQ-5D	**Day 14 & 21** (+/-2)	**QoL Booklet**◊ or **Patient Diary**	• Call patient weekly (if discharged) to check if any problems
EQ-5D & SF-12	**Day 30** (+14)	**QoL Booklet**◊ or **Patient Diary**	
WHQ	**Day 30***	**Patient Diary**	• Completed by patient on day of Day 30 assessment independently
Daily questions	**Post-Day 30*** if ongoing SSI	**Patient Diary (Continuing Involvement)**	• Extra diary only for participant with ongoing SSI at Day 30 assessment.

◊ Based on feedback from feasibility phase, we suggest using the booklets whilst the patient is in hospital

Health-related Quality of Life

SUNRRISE

- Assessed by EQ-5D-5L & SF-12 questionnaires and daily questions in the Patient Diary

  Booklet and diary supplies… Contact the Trial Office surrise@trials.bham.ac.uk
- Assessed at:
  - **Baseline: QoL Booklet (EQ-5D-5L and SF-12)**
    - After consent and **Prior** to surgery (where patient is able to complete)
    - Patients are to provide responses to the questions relating to their health **before** the episode that lead to an emergency laparotomy being required
  - **Day 7: EQ-5D-5L and SF-12**
    - Included in Patient Diary but QoL booklet can be used if still an in-patient
  - **Day 14 & 21: EQ-5D-5L**
    - Included in Patient Diary but QoL booklet can be used if still an in-patient
    - Research team to call patient weekly (if discharged) to check if any problems
  - **Day 30: EQ-5D-5L and SF-12**
    - Included in Patient Diary but QoL booklet can be used if necessary

Based on feedback from feasibility phase, we suggest using the booklets whilst the patient is in hospital

Health-related Quality of Life

SUNRRISE

Patient Diary

- Diary contains:
  - Daily questions relating to wound and health resource usage
  - EQ-5D-5L and SF-12 included at required time points
  - Wound Health Questionnaire
- To be given to patient on discharge for daily completing until the day 30 assessment
  - Add Trial Number and dates to the diary, and cross-out "days" that are not needed
  - Also give a pre-addressed, freepost envelope
- Wound Health Questionnaire
  - This is found at the end of the Patient Diary
  - To be complete by patient **before** Day 30 wound assessment
    - Check it has been completed, and if not, ask the patient to do so before conducting review
    - Does not need to be completed if the patient is an inpatient

Health-related Quality of Life

SUNRRISE

Patient Diary

- At the day 30 assessment…
  - if undertaken in-person, collect completed diary from the patient
  - if undertaken remotely, ask the patient to post it using pre-addressed, freepost envelope

If the patient has not completed the diary, for whatever reason, whilst unfortunate it does not negate the requirement for the day 30 assessment

- If SSI still present (ongoing SSI) at Day 30, patient to be asked to complete further diary; **Patient Diary (Continuing Involvement)**
  - Give/post diary to patient along with pre-addressed, freepost envelope (to return completed diary)
  - To be completed until healed/SSI resolved i.e. discharged from district nursing care
  - Regularly contact patient to check if any problems AND to find out if additional Continuing Involvement diary needed

Follow Up

SUNRRISE

Time point	Activity	CRF
Immediately post-op		In-theatre Form

- **The allocation should not be recorded in the operative note/patient records**
  - State that the patient is participating in the SUNRRISE Trial and the dressing used was either SUNPD or surgeon's preference – labels/stickers are provided

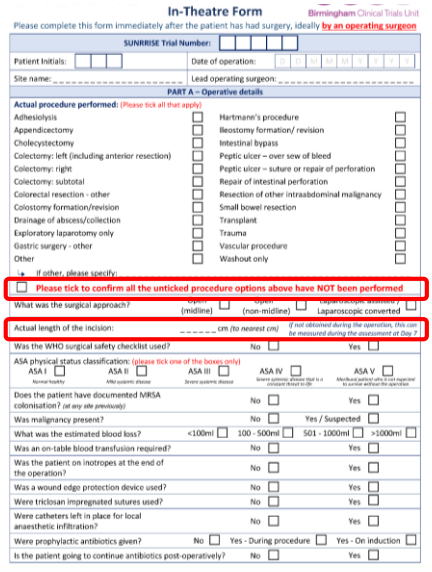
- It may not be possible to prevent any mention in the patient's medical e.g. by ward staff during the patient's admission.
  - The first wound review at day 7 (or discharge if sooner) is not blinded and so is not impacted
  - The second wound review at day 30 is blinded so measures must be take to ensure the assessor is blind to the allocation – the CRF for that assessment asked the assessor to confirm they are blind.

Remember to send out the GP letter

Follow Up

SUNRRISE

Tips on completing the In-theatre Form…


In-Theatre Form

Birmingham Clinical Trials Unit

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

SUNRRISE Trial Number:

Patient Initials: Date of operation: D D M M Y Y Y Y

Site name: Lead operating surgeon:

PART A – Operative details

Actual procedure performed: (Please tick all that apply)

Adhesiolysis	☐	Hartmann's procedure	☐
Appendicectomy	☐	Ileostomy formation/ revision	☐
Cholecystectomy	☐	Intestinal bypass	☐
Colectomy: left (including anterior resection)	☐	Peptic ulcer – over sew of bleed	☐
Colectomy: right	☐	Peptic ulcer – suture or repair of perforation	☐
Colectomy: subtotal	☐	Repair of intestinal perforation	☐
Colorectal resection - other	☐	Resection of other intraabdominal malignancy	☐
Colostomy formation/revision	☐	Small bowel resection	☐
Drainage of abscess/collection	☐	Transplant	☐
Exploratory laparotomy only	☐	Trauma	☐
Gastric surgery - other	☐	Vascular procedure	☐
Other	☐	Washout only	☐

↳ If other, please specify:

☐ Please tick to confirm all the unticked procedure options above have NOT been performed

What was the surgical approach? Open: ☐ (midline) Open: ☐ (non-midline) Open/Converted: ☐ Laparoscopic converted ☐

Actual length of the incision: _____ cm (to nearest cm) If not obtained during the operation, this can be measured during the assessment at Day 7

Was the WHO surgical safety checklist used? No ☐ Yes ☐

ASA physical status classification: (please tick one of the boxes only)

ASA I ☐ Normal healthy | ASA II ☐ Mild systemic disease | ASA III ☐ Severe systemic disease | ASA IV ☐ Severe systemic disease that is a constant threat to life | ASA V ☐ Moribund patient who is not expected to survive without the operation

Does the patient have documented MRSA colonisation? (at any site previously)	No ☐	Yes ☐
Was malignancy present?	No ☐	Yes / Suspected ☐
What was the estimated blood loss?	<100ml ☐ 100 - 500ml ☐ 501 - 1000ml ☐ >1000ml ☐	
Was an on-table blood transfusion required?	No ☐	Yes ☐
Was the patient on inotropes at the end of the operation?	No ☐	Yes ☐
Was a wound edge protection device used?	No ☐	Yes ☐
Were triclosan impregnated sutures used?	No ☐	Yes ☐
Were catheters left in place for local anaesthetic infiltration?	No ☐	Yes ☐
Were prophylactic antibiotics given?	No ☐ Yes - During procedure ☐	Yes - On induction ☐
Is the patient going to continue antibiotics post-operatively?	No ☐	Yes ☐

In-Theatre Form

Birmingham Clinical Trials Unit

Please complete this form immediately after the patient has had surgery, ideally by an operating surgeon

Skin prep used:	Aqueous betadine ☐	0.5% Aqueous Chlorhexidine ☐	2% Aqueous Chlorhexidine ☐	
(please tick only one)	Alcoholic betadine ☐	0.5% Alcoholic Chlorhexidine ☐	2% Alcoholic Chlorhexidine ☐	
	Other ☐	If other, please specify:		
Was adhesive or 'incise' drape used?	No ☐	Yes – iodine-impregnated ☐	Yes – plain incise drape ☐	
Was a wound/incision wash performed?	No ☐	Yes – Betadine ☐	Yes – Saline / Water ☐	Yes – other ☐
Before closing, were gloves changed?			No ☐	Yes ☐
Before closing, were instruments changed?			No ☐	Yes ☐
How was the skin closed?	Staples ☐	Interrupted sutures ☐	Continuous sutures ☐	
Grade of operating surgeon:	Consultant ☐	Registrar level ☐	SHO level ☐	ANP level ☐
Grade of surgeon closing fascia:	Consultant ☐	Registrar level ☐	SHO level ☐	ANP level ☐
Grade of surgeon closing skin:	Consultant ☐	Registrar level ☐	SHO level ☐	ANP level ☐
Total duration of operation:				

PART B – COVID-19

Does the patient have any COVID-19 symptoms on the day of surgery?			No ☐	Yes ☐
Does the patient have proven antibodies to SARS-CoV-2?	No ☐	Yes ☐	Not tested/ Not known ☐	
What is the patient's SARS-CoV-2 virus status on the day of surgery?		Screened positive ☐	Screened negative ☐	
		Screened but result unknown ☐	Not screened ☐	
Has the patient had a positive SARS-CoV-2 swab result or clinical diagnosis of COVID-19?			No or Unknown ☐	Yes ☐
↳ If Yes, how long before surgery was the diagnosis?	Day of Surgery ☐	1-7 days ☐	8-14 days ☐	
	15-28 days ☐	5-6 weeks ☐	7-8 weeks ☐	3-4 months ☐	5-6 months ☐	6+ months ☐

PART C – Dressing

What dressing was applied to the laparotomy wound? (please tick all that apply)

SUNPD ☐ Conventional occlusive dressing ☐ Skin glue ☐ No dressing ☐ Other ☐ If other, please specify:

↳ If SUNPD: Size of dressing used: 10cm x 20cm ☐ 10cm x 30cm ☐ 10cm x 40cm ☐ Other (specify below) ☐

LOT number: If other, please specify:

Was the dressing applied in accordance with the randomised allocation? Yes ☐ No ☐

↳ If no, please provide the reason for non-compliance:

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date: D D M M M M Y Y Y Y

PI declaration – I can confirm that the data reported on this form are accurate.

Full Name (PRINT NAME):

Signature: Date: D D M M M M Y Y Y Y

Trial Schema: Detailed – Follow-up

SUNRRISE

Summary of trial events, time points and activities associated with FU

SITE ACTIVITY	EVENT / TIME POINT	PATIENT ACTIVITY
SUNPD removed (if present) Complete Day 7 CRF and assess the wound Add TNo to Patient diary, cross out unnecessary pages and give to patient Arrange Day 30 follow-up	Day 5-10 post-op (or at discharged if sooner)	Comment on wound pain and dressing acceptability Complete QoL
Contact patient on Day 14 and 21 to ensure Patient Diary (including QoL) are being completed	Between discharge and follow-up	Complete Patient Diary: • Daily questions • EQ-5D on Day 14 and 21
BLINDED assessment of wound Complete Day 30 CRF Collect Patient Diary Ensure Day 30 QoL have been completed *If ongoing SSI*, add TNo to Patient diary (Continuing Involvement) and give to patient	Day 30-44 post-op	Before review, complete Bluebelle wound healing questionnaire (ideally at home) Complete QoL Comment on wound pain
Contact patient regularly to ensure Patient Diary being completed and to arrange return	If ongoing SSI After Day 30 assessment	Complete Patient Diary: • Daily questions
Complete Return to Theatre form	Any time between the operation and Day 30	Returns to theatre
Complete SAE form within 24 hours of becoming aware and send to BCTU straightaway		Experiences an SAE (e.g. prolonged hospital stay or re-admission)

Follow Up

SUNRRISE

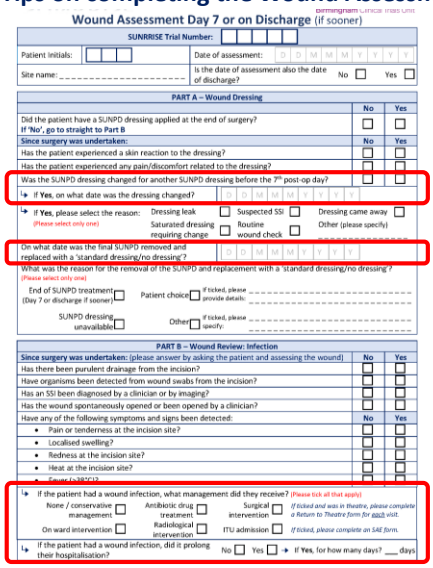
Time point	Activity	CRF
5-10 days post-op (or discharge if sooner)	Wound review by assessor	Wound Assessment Day 7 (or discharge if sooner)

- **Review for day 7 wound assessment…**
  - **Should not be earlier than 5 days post-op UNLESS completed on discharge**
  - **Should not be later than 10 days post-op**
  - **Undertaken as in-person review with visualisation of wound**
    - **If discharged unexpectedly, contact patient to complete review remotely and document this (e.g. file note sent will CRF or annotation on CRF**
  - **Assesses the period from index operation to date of assessment; discussion with patient, review of medical notes and as well as visual inspection of the wound**
- **Day 7 wound assessor should be trained** but does not have to be blind to the allocation
- **Removal of intervention (SUNPD)** on day 7 at the latest
  - *If the wound assessment on day 5, the SUNPD is removed on day 5 and the wound assessment is performed*
  - *If the wound assessment on day 9, the SUNPD is removed on day 7 and replaced with a standard dressing and on day 9 when the wound is reviewed*

Follow Up

SUNRRISE

Tips on completing the Wound Assessment Day 7 or Discharge (if sooner) CRF…


Wound Assessment Day 7 or on Discharge (if sooner)

SUNRRISE Trial Number:

Patient Initials: Date of assessment: D D M M M Y Y Y Y

Site name: Is the date of assessment also the date of discharge? No Yes

PART A – Wound Dressing

	No	Yes
Did the patient have a SUNPD dressing applied at the end of surgery? If 'No', go to straight to Part B		
Since surgery was undertaken:	**No**	**Yes**
Has the patient experienced a skin reaction to the dressing?		
Has the patient experienced any pain/discomfort related to the dressing?		
Was the SUNPD dressing changed for another SUNPD dressing before the 7th post-op day?		

If Yes, on what date was the dressing changed? D D M M M Y Y Y Y

If Yes, please select the reason: (Please select only one) Dressing leak, Suspected SSI, Dressing came away, Saturated dressing requiring change, Routine wound check, Other (please specify)

On what date was the final SUNPD removed and replaced with a 'standard dressing/no dressing'? D D M M M Y Y Y Y

What was the reason for the removal of the SUNPD and replacement with a 'standard dressing/no dressing'? (Please select only one)

End of SUNPD treatment (Day 7 or discharge if sooner), Patient choice, If ticked, please provide details:

SUNPD dressing unavailable, Other, If ticked, please specify:

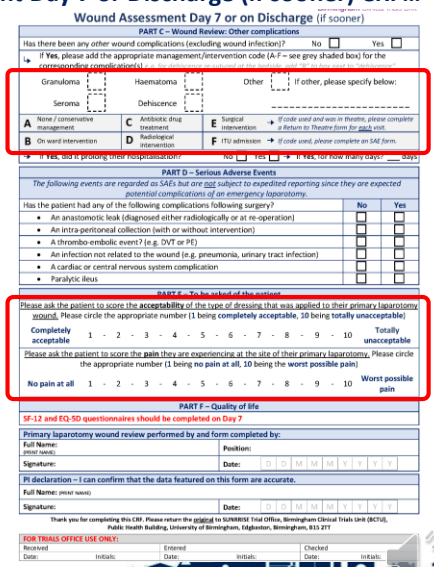
PART B – Wound Review: Infection

Since surgery was undertaken: (please answer by asking the patient and assessing the wound)	**No**	**Yes**
Has there been purulent drainage from the incision?		
Have organisms been detected from wound swabs from the incision?		
Has an SSI been diagnosed by a clinician or by imaging?		
Has the wound spontaneously opened or been opened by a clinician?		
Have any of the following symptoms and signs been detected:	**No**	**Yes**
• Pain or tenderness at the incision site?		
• Localised swelling?		
• Redness at the incision site?		
• Heat at the incision site?		
• Fever (>38°C)?		

If the patient had a wound infection, what management did they receive? (Please tick all that apply)

None / conservative management, Antibiotic drug treatment, Surgical intervention (If ticked and was in theatre, please complete a Return to Theatre form for each visit.), On ward intervention, Radiological intervention, ITU admission (If ticked, please complete an SAE form.)

If the patient had a wound infection, did it prolong their hospitalisation? No Yes → If Yes, for how many days? ___ days


Wound Assessment Day 7 or on Discharge (if sooner)

PART C – Wound Review: Other complications

Has there been any other wound complications (excluding wound infection)? No Yes

If Yes, please add the appropriate management/intervention code (A-F – see grey shaded box) for the corresponding complication(s).

Granuloma, Haematoma, Other, If other, please specify below:

Seroma, Dehiscence

A None / conservative management, C Antibiotic drug treatment, E Surgical intervention → If code used and was in theatre, please complete a Return to Theatre form for each visit.

B On ward intervention, D Radiological intervention, F ITU admission → If code used, please complete an SAE form.

If Yes, did it prolong their hospitalisation? No Yes → If Yes, for how many days? ___ days

PART D – Serious Adverse Events

The following events are regarded as SAEs but are not subject to expedited reporting since they are expected potential complications of an emergency laparotomy.

Has the patient had any of the following complications following surgery?	No	Yes
• An anastomotic leak (diagnosed either radiologically or at re-operation)		
• An intra-peritoneal collection (with or without intervention)		
• A thrombo-embolic event? (e.g. DVT or PE)		
• An infection not related to the wound (e.g. pneumonia, urinary tract infection)		
• A cardiac or central nervous system complication		
• Paralytic ileus		

PART E – To be asked of the patient

Please ask the patient to score the acceptability of the type of dressing that was applied to their primary laparotomy wound. Please circle the appropriate number (1 being completely acceptable, 10 being totally unacceptable)

Completely acceptable 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 Totally unacceptable

Please ask the patient to score the pain they are experiencing at the site of their primary laparotomy. Please circle the appropriate number (1 being no pain at all, 10 being the worst possible pain)

No pain at all 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 Worst possible pain

PART F – Quality of life

SF-12 and EQ-5D questionnaires should be completed on Day 7

Primary laparotomy wound review performed by and form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date: D D M M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate.

Full Name: (PRINT NAME)

Signature: Date: D D M M M Y Y Y Y

Thank you for completing this CRF. Please return the original to SUNRRISE Trial Office, Birmingham Clinical Trials Unit (BCTU), Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT

FOR TRIALS OFFICE USE ONLY:

Received Date: Initials: Entered Date: Initials: Checked Date: Initials:

Follow Up

SUNRRISE

Time point	Activity	CRF
30-44 days post-op	Wound review by assessor BLIND to allocation	Wound Assessment Day 30

- **Ensure patient's review for 30 day wound assessment is arranged**
  - **MUST not be earlier than 30 days post-op**
  - **Should not be later than 44 days post-op**
  - **Undertaken either:**
    - **In-person review with visualisation of wound**
    - **Remotely by real-time remote video consultation**
  - **Assesses the period from index operation to 30 days; discussion with Patient, consideration of Patient Diary, review of medical notes as well as visual inspection of the wound**
- Ensure 30 day wound assessor is **blind to the allocation** (dressing used) and **trained**
  - someone not previously involved in the patient care, nor had site of the previously completed CRFs
  - Avoid accidental unbinding - assessor should complete the wound assessment (Part A & B of CRF) before consulting medical notes to assist with other parts of CRF

How will this be arranged at your site? Who by? When?

Follow Up

SUNRRISE

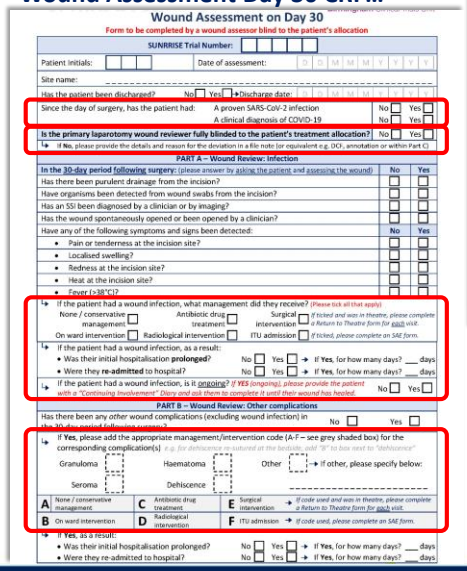
Time point	Activity	CRF
30-44 days post-op	Wound review by assessor BLIND to allocation	Wound Assessment Day 30

- The **primary endpoint** assessed so it is critical the review is completed at the time and in the manner required in the protocol
  - Arrange early and discuss with participant
  - Check when calling patients at Day 14 and Day 21 if will still be attending so can address any problems as early as possible
- **REMEMBER:** £10 reimbursement to each participant towards travel expenses where day 30 review is completed in-person
  - The format this takes and logistics are to be decided locally
- If this is not achieved:
  - it should be completed as soon as possible after day 44 – a late assessment will still provide valuable data
    ensure PI is made aware
  - As for all protocol deviations, the reason it was not achieved needs to be provided – the CRF allows for this information to be recorded

Follow Up

SUNRRISE

Tips on completing the Wound Assessment Day 30 CRF…


Wound Assessment on Day 30

Form to be completed by a wound assessor blind to the patient's allocation

SUNRRISE Trial Number:

Patient Initials: Date of assessment:

Site name:

Has the patient been discharged? No Yes → Discharge date:

Since the day of surgery, has the patient had: A proven SARS-CoV-2 infection No Yes; A clinical diagnosis of COVID-19 No Yes

Is the primary laparotomy wound reviewer fully blinded to the patient's treatment allocation? No Yes

If No, please provide the details and reason for the deviation in a file note (or equivalent e.g. DCF, annotation or within Part C)

PART A – Wound Review: Infection

In the 30-day period following surgery: (please answer by asking the patient and assessing the wound)	No	Yes
Has there been purulent drainage from the incision?		
Have organisms been detected from wound swabs from the incision?		
Has an SSI been diagnosed by a clinician or by imaging?		
Has the wound spontaneously opened or been opened by a clinician?		
Have any of the following symptoms and signs been detected:	No	Yes
• Pain or tenderness at the incision site?		
• Localised swelling?		
• Redness at the incision site?		
• Heat at the incision site?		
• Fever (>38°C)?		

If the patient had a wound infection, what management did they receive? (Please tick all that apply)

None / conservative management; Antibiotic drug treatment; Surgical intervention (If ticked and was in theatre, please complete a Return to Theatre form for each visit.); On ward intervention; Radiological intervention; ITU admission (If ticked, please complete an SAE form.)

If the patient had a wound infection, as a result:
• Was their initial hospitalisation **prolonged**? No Yes → If Yes, for how many days? ___ days
• Were they **re-admitted** to hospital? No Yes → If Yes, for how many days? ___ days

If the patient had a wound infection, is it ongoing? If YES (ongoing), please provide the patient with a "Continuing Involvement" Diary and ask them to complete it until their wound has healed. No Yes

PART B – Wound Review: Other complications

Has there been any *other* wound complications (excluding wound infection) in the 30-day period following surgery? No Yes

If Yes, please add the appropriate management/intervention code (A-F – see grey shaded box) for the corresponding complication(s) e.g. for dehiscence re-sutured in the theatre, add 'E' to box next to 'Dehiscence'

Granuloma; Haematoma; Other → If other, please specify below:

Seroma; Dehiscence

A None / conservative management; C Antibiotic drug treatment; E Surgical intervention → If code used and was in theatre, please complete a Return to Theatre form for each visit.

B On ward intervention; D Radiological intervention; F ITU admission → If code used, please complete an SAE form.

If Yes, as a result:
• Was their initial hospitalisation prolonged? No Yes → If Yes, for how many days? ___ days
• Were they re-admitted to hospital? No Yes → If Yes, for how many days? ___ days

PART C – Wound Review: Method and timing

The protocol requires wound review be undertaken in-person (or by remote video consultation at 30-44 days post-operatively. If this is not achieved, either in how the review is completed or when it is done, the details and reasons for the deviation need to be documented.

How was the review conducted? In-person with visualisation of wound; Remotely with visualisation of wound by video call; Remotely without visualisation of wound by telephone call → Please explain why below; Other → If Other, please specify: → Please explain why below

If NOT conducted as required in the protocol, please explain why:

Was the wound review completed in the window required in the protocol? No Yes

If NOT conducted when required in the protocol, please explain why:

PART D – Serious Adverse Events

The following events are regarded as SAEs but are not subject to expedited reporting since they are expected potential complications of an emergency laparotomy.

Has the patient had any of the following complications following surgery?	No	Yes
• An anastomotic leak (diagnosed either radiologically or at re-operation)		
• An intra-peritoneal collection (with or without intervention)		
• A thrombo-embolic event? (e.g. DVT or PE)		
• An infection not related to the wound (e.g. pneumonia, urinary tract infection)		
• A cardiac or central nervous system complication		
• Paralytic ileus		

PART E – Wound Heath Questionnaire (to be asked of the patient)

This is a repeat of the questionnaire in the diary. Please ask the questions and give options to the patient. Under each heading, please tick the ONE box that is most relevant to their experience.

Since you left hospital after having surgery....	Not at all	A little	Quite a bit	A lot
1. Was there redness spreading away from the [illegible]schema/cellulitis)				
17. Has your wound be… abscess)				
18. Have you had an operation under general anaesthetic for treatment of a problem with your wound?				

PART F – Wound Pain (to be asked of the patient)

Please ask the patient to score the **pain** they are experiencing at the site of their primary laparotomy wound. Please circle the appropriate number (1 being no pain at all, 10 being the worst possible pain)

No pain at all 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 Worst possible pain

PART G - Quality of life

SF-12 and EQ-5D questionnaires should be completed on Day 30.

Primary laparotomy wound review performed by and form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date:

Discontinuation & Withdrawal

SUNRRISE

- Patients may withdraw at any time
- If a patient decides to withdraw the details should be documented in the medical notes and the **SUNRRISE** Trial Office informed ASAP using the Patient Discontinuation Form

In SUNRRISE, withdrawal is a <u>patient</u> decision AND they can selectively withdraw.

A patient should be followed up no matter what "happens" unless the patient specifically decides they wish to withdraw.

- For patient's who withdraw and agree to the collection of routinely recorded information, along with those that die or are lost to follow-up, where possible data will be provided based on the information in the patient's medical notes.

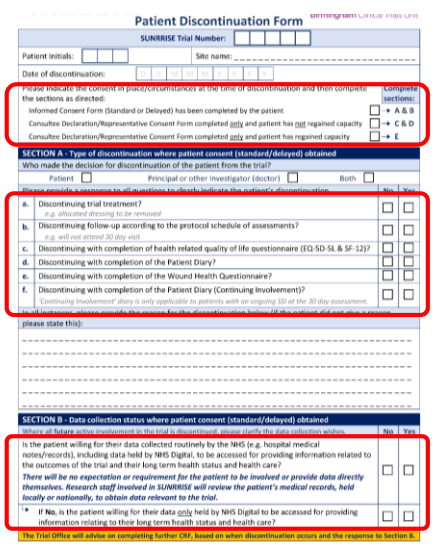
Discontinuation & Withdrawal

Example of types of withdrawal in **SUNRRISE** may include:

- **Withdrawal from trial-specific treatment:**
  - Patient will not complete treatment as per the **SUNRRISE** protocol. Follow-up according to the protocol would still be requested
- **Withdrawal from trial-specific follow-up:**
  - Patient has had trial treatment but does not wish to be followed up according to the protocol
  - The patient will be followed up according to standard practice
  - It must be confirmed that the patient has agreed that follow-up data collected at standard clinic visits may be used in the final analysis
- **Complete withdrawal:**
  - Patient is not willing to be followed up for trial purposes at any further visits, i.e. only data collected prior to the withdrawal of consent can be used in the final analysis

Discontinuation & Withdrawal

Tips on completing the Patient Discontinuation Form…


Patient Discontinuation Form

SUNRRISE Trial Number:

Patient Initials: Site name:

Date of discontinuation:

Please indicate the consent in place/circumstances at the time of discontinuation and then complete the sections as directed: Complete sections:

Informed Consent Form (Standard or Delayed) has been completed by the patient → A & B

Consultee Declaration/Representative Consent Form completed only and patient has not regained capacity → C & D

Consultee Declaration/Representative Consent Form completed only and patient has regained capacity → E

SECTION A - Type of discontinuation where patient consent (standard/delayed) obtained

Who made the decision for discontinuation of the patient from the trial?

Patient Principal or other Investigator (doctor) Both

Please provide a response to all questions to clearly indicate the patient's discontinuation. No Yes

a. Discontinuing trial treatment? e.g. allocated dressing to be removed

b. Discontinuing follow-up according to the protocol schedule of assessments? e.g. will not attend 30 day visit

c. Discontinuing with completion of health related quality of life questionnaire (EQ-5D-5L & SF-12)?

d. Discontinuing with completion of the Patient Diary?

e. Discontinuing with completion of the Wound Health Questionnaire?

f. Discontinuing with completion of the Patient Diary (Continuing Involvement)? 'Continuing Involvement' diary is only applicable to patients with an ongoing SSI at the 30 day assessment.

In all instances, please provide the reason for the discontinuation below (if the consultee/representative did not give a reason, please state this):

SECTION B - Data collection status where patient consent (standard/delayed) obtained

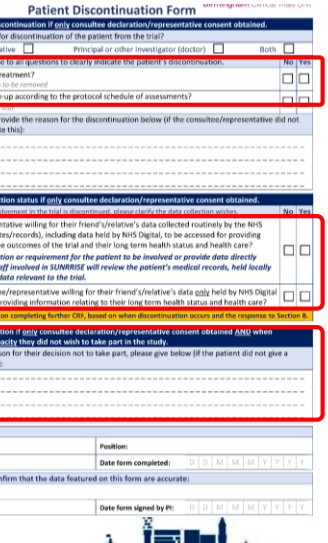
Where all future active involvement in the trial is discontinued, please clarify the data collection wishes. No Yes

Is the patient willing for their data collected routinely by the NHS (e.g. hospital medical notes/records), including data held by NHS Digital, to be accessed for providing information related to the outcomes of the trial and their long term health status and health care?

There will be no expectation or requirement for the patient to be involved or provide data directly themselves. Research staff involved in SUNRRISE will review the patient's medical records, held locally or nationally, to obtain data relevant to the trial.

If No, is the patient willing for their data only held by NHS Digital to be accessed for providing information relating to their long term health status and health care?

The Trial Office will advise on completing further CRF, based on when discontinuation occurs and the response to Section B.


Patient Discontinuation Form

SECTION C – Type of discontinuation if only consultee declaration/representative consent obtained.

Who made the decision for discontinuation of the patient from the trial?

Consultee/representative Principal or other Investigator (doctor) Both

Please provide a response to all questions to clearly indicate the patient's discontinuation. No Yes

a. Discontinuing trial treatment? e.g. allocated dressing to be removed

b. Discontinuing follow-up according to the protocol schedule of assessments? e.g. will not attend 30 day visit

In all instances, please provide the reason for the discontinuation below (if the consultee/representative did not give a reason, please state this):

SECTION D - Data collection status if only consultee declaration/representative consent obtained.

Where all future active involvement in the trial is discontinued, please clarify the data collection wishes. No Yes

Is the consultee/representative willing for their friend's/relative's data collected routinely by the NHS (e.g. hospital medical notes/records), including data held by NHS Digital, to be accessed for providing information related to the outcomes of the trial and their long term health status and health care?

There will be no expectation or requirement for the patient to be involved or provide data directly themselves. Research staff involved in SUNRRISE will review the patient's medical records, held locally or nationally, to obtain data relevant to the trial.

If No, is the consultee/representative willing for their friend's/relative's data only held by NHS Digital to be accessed for providing information relating to their long term health status and health care?

The Trial Office will advise on completing further CRF, based on when discontinuation occurs and the response to Section B.

SECTION E - Discontinuation if only consultee declaration/representative consent obtained AND when participant regained capacity they did not wish to take part in the study.

If patient provided a reason for their decision not to take part, please give below (if the patient did not give a reason, please state this):

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date form completed: D D M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate:

Full Name: (PRINT NAME)

Signature: Date form signed by PI: D D M M Y Y Y Y

Assessment Schedule

Activity/CRF	Pre-theatre	In-theatre	Day 7 post-op (-2/+3 days)	Day 14 post-op (± 2 days)	Day 21 post-op (± 2 days)	Day 30 post-op (+ 14 days)	Day 30+
Patient identification and screening	On-call surgical team						
Patient consent • Standard	Patient & Member of the research team						
Patient consent • Delayed (UK only)	Consultee/Representative & Member of the research team	Patient & Member of the research team when capacity regained					
Randomisation form	Started pre-theatre by the research team	Surgeon or member of the research team					
In-Theatre form		Ideally an operating surgeon, or member of the research team					
Wound Assessment Day 7 or on Discharge (if sooner)[1,2]			Member of the research team				
EQ-5D-5L	Completed by the participant		Completed by the participant	Completed by the participant	Completed by the participant	Completed by the participant	
SF-12	Completed by the participant		Completed by the participant			Completed by the participant	
Patient diary			Completed daily by the participant following discharge from hospital until they undergo the Day 30 wound review				Patients to continue with a diary if they have an ongoing SSI
Bluebelle wound healing questionnaire						Completed by the participant independently, and then by the participant with a blinded member of the research team reviewing wound	
Wound Assessment Day 30[1]						Completed by a blinded member of the research team as an **in-person or remote (video) review**	
SAE reporting		All serious adverse events by member of the research team using SAE form or wound assessment CRF if excluded from expedited reporting					Related serious adverse events only
Return to theatre form		Member of the research team for any return to theatre following patient returning to theatre					
PI Declaration form for CFR data							Completed by PI at the end of each participant's involvement

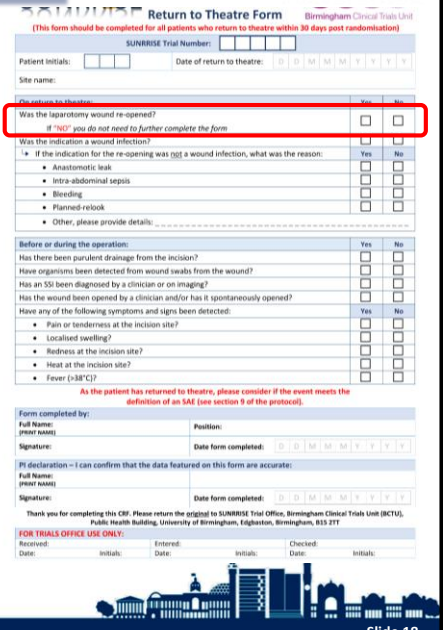
[1] Assessment of pain undertaken by a member of the research team by asking the participant and recording the response on the CRF
[2] Score of patient acceptability of dressing undertaken by a member of the research team by asking the participant and recording the response on the CRF

Return to theatre

- CRF to be completed for any returns to theatre
- If the laparotomy wound is <u>not</u> reopened only the first question needs to be completed

Intervention following a return to theatre…

- If SUNPD removed during a theatre visit <u>and</u> within 7 days of the index laparotomy, <u>SUNPD will be reapplied</u> to the wound at the end of the procedure
  - **The treatment period remains 7 days from the index laparotomy.**
- If theatre visit is after 7 days of the index laparotomy, regardless of the randomised allocation, at the end of the operation a dressing of the surgeon's choice will be applied (as long as this is not a SUNPD)



Return to Theatre Form — Birmingham Clinical Trials Unit

(This form should be completed for all patients who return to theatre within 30 days post randomisation)

SUNRRISE Trial Number:

Patient Initials: Date of return to theatre: D D M M Y Y Y Y

Site name:

On return to theatre:	Yes	No
Was the laparotomy wound re-opened?	☐	☐
If "NO" you do not need to further complete the form		
Was the indication a wound infection?	☐	☐
If the indication for the re-opening was not a wound infection, what was the reason:	Yes	No
• Anastomotic leak	☐	☐
• Intra-abdominal sepsis	☐	☐
• Bleeding	☐	☐
• Planned-relook	☐	☐
• Other, please provide details:	☐	☐

Before or during the operation:	Yes	No
Has there been purulent drainage from the incision?	☐	☐
Have organisms been detected from wound swabs from the wound?	☐	☐
Has an SSI been diagnosed by a clinician or on imaging?	☐	☐
Has the wound been opened by a clinician and/or has it spontaneously opened?	☐	☐
Have any of the following symptoms and signs been detected:	Yes	No
• Pain or tenderness at the incision site?	☐	☐
• Localised swelling?	☐	☐
• Redness at the incision site?	☐	☐
• Heat at the incision site?	☐	☐
• Fever (>38°C)?	☐	☐

As the patient has returned to theatre, please consider if the event meets the definition of an SAE (see section 9 of the protocol).

Form completed by:

Full Name: (PRINT NAME) Position:

Signature: Date form completed: D D M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate:

Full Name: (PRINT NAME)

Signature: Date form completed: D D M M Y Y Y Y

Thank you for completing this CRF. Please return the original to SUNRRISE Trial Office, Birmingham Clinical Trials Unit (BCTU), Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT

FOR TRIALS OFFICE USE ONLY:

Received: Date: Initials: Entered: Date: Initials: Checked: Date: Initials:

Case report forms (CRF)

SUNRRISE

- CRFs will be paper records completed on site
  - CRFs are considered complete when all data fields are completed unambiguously or the data is marked as unobtainable
- Corrections should made by:
  - Striking through incorrect entry with a single line (without obscuring the original entry) ~~2016~~
  - Entering correct information adjacent to incorrect entry ~~2016~~ 2017
  - Including initials and date ~~2016~~ 2017 JB 22-Sep-2018
- Principal Investigator (or delegate) must:
  - Promptly review and sign-off CRF data at the end of a participant's involvement *(PI only)*
  - Sign and date Inclusion/Exclusion Criteria (randomisation form) *(PI or delegate)*
- Originals to be returned to the **SUNRRISE** Trial Office and true copies kept at site, EXCEPT the consent/declaration forms where a copy will be sent to the **SUNRRISE** Trial Office and original kept at site in ISF
  - We suggest posting consent/declaration and randomisation forms (as they contain patient identifiers) together but separately to other forms
- Guidelines are provided in the Investigator Site File

Questions about completing CRFs?
Get in touch…
0121 414 9012 / 077 8510 2378
sunrrise@trials.bham.ac.uk

Supplies of CRFs (paper or electronic)… Contact the Trial Office sunrise@trials.bham.ac.uk

Case report forms (CRF)

SUNRRISE

CRF Name	Contents	Window	Duty on log required for completion	Training Required
Randomisation	Eligibility criteria checklist, confirmation of eligibility, operative details, demographics, allocation	n/a	K, *For eligibility section of form*: D (doctors only)	Study-specific
In-theatre	Further operative details, allocation delivery	n/a	J	Study-specific
Wound Assessment Day 7 or on Discharge (if sooner)	SUNPD treatment (if applicable), unblinded Wound Review for infections and complications and SAEs.	Day 5-10	K **&** O	Study-specific **&** Wound Assessment
Wound Assessment Day 30-37	Eligibility criteria checklist, confirmation of eligibility, operative details demographic data, allocation	Day 30-44	K **&** O	Study-specific **&** Wound Assessment
Return to Theatre	Return to theatre details, Wound Review for infection	n/a	K & *ideally* O	Study-specific & *ideally* Wound Assessment
Patient Discontinuation	Type of discontinuation(s), reasons for discontinuation(s), data collection status	n/a	K	Study-specific
PI Declaration Form for CRF Data	Confirmation of completeness and accuracy of all CRF data	n/a	M	Study-specific
SAE	Event information, seriousness and causality		H, *For causality section of form*: I (PI only)	Study-specific

Delegation log duties: **D**. Confirm patient eligibility (doctors only), **H**. SAE reporting, **I**. Causality assessment of SAE (PI only), **J**. Completion of In-Theatre Form and assoc. DCFs, **K**. Completion of other CRFs and assoc. DCFs, M. CRF review and sign off & SDV (PI only*), **O**. Wound assessment

CRFs are expected within to arrive at the Trial Office within 7 days of completion – after this reminders with be sent

Data clarification forms (DCF)

- All missing, erroneous and/or ambiguous data will be queried via a DCF
  - Each query is assigned a unique reference number
- Query resolutions should always be provided on the DCF form (or as part of a file note)
- **No changes should ever be made to the copy of the completed CRF after the original has been sent to the SUNRRISE Trial office**
- DCF should be completed by anyone that has been delegated the duties of completing CRFs and DCFs
- The original completed DCF should be returned to the **SUNRRISE** Trial office
- A photocopy of the DCF should be kept at site it should be attached to the associated CRF

Staff from BCTU will transcribe data from paper CRFs and DCFs into the trial database

PI declaration for CRF Data

- PI is required to compete "Declaration Form for CRF Data" for each participant
  - Once all required CRFs have been completed and provided to the SUNRRISE Trial Office, and any data queries resolved
  - Review CRFs and confirm all data featured are accurate
  - Due approximately 3 weeks after the Day 30 assessment is completed BUT it may be preferred to wait until it is requested by the **SUNRRISE** Trial Office, who will only do so after all (if any) query are resolved
- CRFs may include a "PI declaration" section BUT following the implementation of the "Declaration Form for CRF Data", this does not need to be completed on the individual CRFs before sending to the **SUNRRISE** Trial Office
  - This was originally used to document the local PI confirmation that all the data featured on the form are accurate and demonstrate oversight
  - This section has been retain to allow this mode of data sign-off to continue if preferred

Source data

- Source data is defined as: all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial
- QoL questionnaires and Patient Diaries will be considered source data. This data is entered directly onto the forms and these are clearly identified and detailed below:
  - EQ-5D-5L
  - SF-12
  - Patient Diary
- **The CRFs are not the source data for clinical information**
- In order to allow for the accurate reconstruction of the trial and clinical management of the participant, source data will be accessible and maintained
- **Source data (except for QoL) is kept as part of the participants' medical notes, generated and maintained at site**

Source data

- Medical notes to be completed following consultations with the participants
- All entries to be signed and dated by the person making the entry (or equivalent according to local systems/policies)
  - where decision made by someone other than the staff making the entry they too should also sign and date the entry e.g. nurse making the entry but the decision is made by a clinician
- Include who is responsible for completing the source data i.e. the research team or the participant (for example in the use of questionnaires)
- Key events to be recorded include:
  - date provision of the subject with the PIS
  - date of consent, eligibility decision
  - randomisation
  - treatment and dosing decisions relating to clinical care
  - trial visits/follow-up
  - adverse events
  - withdrawal, termination and end of trial involvement

SUNRRISE

Thank you

Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 4

- Safety reporting

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Safety Reporting

SUNRRISE

Adverse Events (AE)

Any untoward medical occurrence in a participant or clinical trial subject participating in the trial which does not necessarily have a causal relationship with the intervention received.

- All AEs should be should be documented in the patient's medical notes and assessed for seriousness and causality (relatedness)
- The safety profile of the SUNPD is well characterised so unlikely the SUNRRISE will reveal any new safety information
- Only data on selected events within 30-days post-surgery period will be collected in SUNRRISE/reported to the trial office
- AEs collected/reported on the Wound Assessment Day 7 CRF:
  - Skin reaction to the applied dressing
  - Pain/discomfort related to the applied dressing

Safety Reporting

SUNRRISE

Serious Adverse Events (SAE)

An untoward occurrence that:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Or is otherwise considered medically significant by the Investigator

- As SUNPD are available and often used within the NHS - there are no SAEs anticipated as a unique consequence of participation in the trial

Expedited reporting of SAEs to BCTU

- All events that meet the above definition, and not otherwise excluded
- However, we expect the following events to always be reported as SAEs:
  - Entero-cutaneous fistula
  - Fascial dehiscence
  - Death

! *Dehiscence if often used to describe the breakdown of the wound where the skin has opened but the fascia is intact - not an SAE as not fascial dehiscence*

Safety Reporting

SUNRRISE

Reporting exclusions

- SAEs that are expected and unrelated **do not require expedited reporting** using the SAE From, instead data within 30-days post-surgery period will be collected using the Wound Assessment Day 7 and Day 30 CRF:
  - Anastomotic leak
  - Paralytic ileus
  - Intra-peritoneal collections (with or without intervention)
  - Thrombo-embolic events
  - Infections not related to the wound (e.g. pneumonia, urinary tract infections)
  - Cardiac or central nervous system complications

- SAEs that are **that are protocol excluded from reporting**:
  - SAEs that are related to symptoms or progression of the participant's disease
  - SAEs that are related to a pre-existing condition
  - Pre-planned hospitalisation

- All SAEs should be documented in the patient's medical note and should be assessed for causality (relatedness)

Safety Reporting

SUNRRISE

SAE reporting

- Reporting period:
  - All events occurring from randomisation to 30 days post-surgery
  - After 30 days post-surgery if event judged to be at least possibly related to the use of SUNPD
- Reporting process:
  - SAE that require expedited reporting…
    - Complete SAE form immediately after becoming aware of the event, certainly no later than **24 hours** after, and fax or email to the Trial Office at BCTU:
      SUNRRISE@trials.bham.ac.uk or **0121 415 8871**
    - Faxed SAE forms must be accompanied by SAE Fax Cover (supplied)
    - Countersigned by the PI (or delegate)
    - Follow-up information must be submitted until clinical recovery
  - SAE that do requiring expedited reporting…
    - Recorded on Wound Assessment CRFs and submitted accordingly
- Report SAEs to your Trust as required by local SOPs

Safety Reporting

SUNRRISE

Damaged/faulty SUNPD and resulting events for manufacturers

- The manufactures of the device (SUNPD) require reporting of:
  - Misuse of device causing a serious injury
  - Any allegation of deficiencies related to the device e.g.
    - Device received damaged, mislabelled, cosmetic or functional issues
    - If the device does not perform as expected due to failure, both post-op and during surgery
- If an adverse event occurs as a consequence of the misused or faulty/damaged device, this also need to be reported.

Contact the SUNRRISE Trial Office as soon as you become aware – we will assist you with the reporting process

- Events that do not need reporting are:
  - Events unrelated to the device
  - Pain not associated with the surgery or the device
  - Events collected for any reason that are unrelated to the device; illness, expected swelling, expected pain, pre-existing conditions, unrelated hospitalisations

SUNRRISE

Thank you

Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 5

- Delegation of duties and training
- Associate PI scheme and authorship policy
- PI oversight
- Compliance, monitoring and audits
- Confidentiality
- Investigator site file
- Archiving

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Delegation Log

SUNRRISE

- A delegation log is provided in the ISF along with guidance on its completion
- **All staff undertaking research activity should sign delegation log and the duties be authorised by the PI prior to performing any study activities**
- PI to complete delegation log too
- CVs (signed & dated) and evidence of GCP training for all staff on delegation log must be present in ISF and provided to the **SUNRRISE** Trial Office
  - These should be updated every three years, ideally two, but Trust requirements may differ
  - **GCP for staff taking consent and confirming eligibility is required, but GCP recommended for all staff**
- Change of staff – the **SUNRRISE** Trial Office must be notified of all staff changes
  - Copies of delegation log to be sent to **SUNRRISE** Trial Office when it is updated; **don't forget to add end ("To") dates**
- Completed delegation logs to be filed in ISF

Delegation Log

- By signing an entry on the delegation log, the PI is confirming that:
  1) The person is authorised to perform the study procedures that the person has detailed in the task section
  2) The person is qualified to undertake these tasks
  3) The person is appropriately informed about the study protocol and relevant study procedures
- No person listed on the delegation log should carry out any study related activity until they have been delegated the duty from the PI
- A persons start date on the study cannot and should not pre-date the date the PI signs their entry on the delegation log

The delegation log may sometimes seem a paper exercise but it is essential - it is documented evidence of the appropriate delegation of the investigator's responsibilities by the PI as part of the their oversight of the trial

Training

General SUNRRISE training (study-specific)

- All staff working on the trial must be trained in the protocol & study procedures before undertaking ANY trial activities and addition to the delegation log
- Provided by **SUNRRISE** team during the SIV and then subsequently disseminated by PI
  - Training videos available online or can be delivered by teleconference/video conference by **SUNRRISE** team upon request)
- Use SIV slides as training material in conjunction with protocol and guidelines covering:
  - Trial overview (background, rationale, trial design)
  - Objectives and outcome
  - Patient eligibility
  - Participant identification and consent
  - Randomisation procedures
  - Trial activities, paperwork, CRFs (and completion of), DCFs
  - Safety reporting
  - Trial supplies

Ensure all staff involved in the trial (directly and indirectly) are aware that before a patient can be randomised, a SUNRRISE-specific consent form must be completed by the patient (or a declaration form by the personal consultee), **especially if they are new to research and/or the trial**

Training

SUNRRISE

SUNPD application training

- To be completed before applying a SUNPD (PICO 7) to the emergency laparotomy wound of a SUNRRISE participant
- Training in the application of SUNPD will be provided by a Smith & Nephew representative prior to sites opening recruitment
- Subsequent training on the application of SUNPD (e.g. of new staff) will be disseminated by the PI
  - Only staff trained in the application of SUNPD should place the dressings

Wound assessment training

- To be completed before reviewing/assessing the emergency laparotomy wound of a SUNRRISE participant and completing the associate CRF
- Wound assessment training will be provided by an online module accessed via the "Training" section of the trial website; www.birmingham.ac.uk/SUNRRISE
  - Only staff that have completed the training module should assess wounds

Training

SUNRRISE

Documenting training

- Evidence of training must be in ISF (section 3)
- Template training log is provided in ISF (it is acceptable to use your own)
  - Online system now available that can be used in concert with paper log; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Other evidence to document training:
  - Minutes from meetings
  - Confirmations provides by online systems associated with SUNRRISE

Authorship

- Published under a corporate authorship policy
  - E.g. 'The SUNRRISE Trial Collaborators, the North West Research Collaborative and the West Midlands Research Collaborative'
- There will be no named authors in the main authorship line but individuals will be named within the paper and roles will be defined
  - All collaborators will be named and will be PubMed citable
- Authors will be listed as per their involvement within each part of the study/manuscript
  - Writing group and list of local collaborators
- To be included in the list of local collaborators, the collaborator needs to have been involved in the pathway of at least 6 participants
  - Local collaborators will be listed according to hospital and then alphabetically; local consultant and trainee leads will be identified

Associate PI Scheme

- Aims to engage, recognise and promote junior doctor engagement in NIHR portfolio research to develop them to be PIs of the future
- Supported by NIHR
- Open to any junior doctor, nurse or allied healthcare professional willing to make a significant contribution to the conduct and delivery of a trial at a local level
- One associate PI per site, per study, at any given time with a minimum commitment term of 6 months
- Full details of the scheme and the associated checklist are available on the NIHR website; https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040
- Please contact the **SUNRRISE** Trial Office with any queries

PI oversight

SUNRRISE

The PI is ultimately responsible for the conduct of the SUNRRISE Trial at the site

- Article 73 of the Clinical Trial Regulation:
  PI must ensure compliance
- Shall assign tasks among members in a way in which safety of subject is not compromised
- Not compromising reliability and robustness of data generated in trial

PI oversight

SUNRRISE

Oversight includes, but is not limited to:

- Ensuring the **decision to include a participant** in a trial is documented in the medical notes:
  - confirmation of eligibility
  - when/who approached the patient and gave them the PIS
  - when/who took consent for entry into trial
- Being able to provide evidence that all team members have received **appropriate training** prior to duties being delegated to them – e.g. training log/records, GCP
- Ensuring the **integrity of the data** being submitted for use in the trial – e.g. sign-off of CRFs

Protocol Compliance

Each Principal Investigator must:

- Read the approved protocol and sign protocol signature page
- Adhere to the approved protocol
- Ensure current protocol is in ISF
- Be responsible for enrolling only those patients who meet eligibility criteria

PROTOCOL SUNRRISE

PI SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Principal Investigator agrees to conduct the trial in compliance with the approved protocol.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

This protocol has been approved by:

Trial Name:	The SUNRRISE Trial
Protocol Version Number:	Version: 3.0
Protocol Version Date:	05 - Aug - 2020
PI Name:	
Name of Site:	
Signature and date:	_____ __/__/____

PI declaration for CRF Data

- PI is required to compete "Declaration Form for CRF Data" for <u>each</u> participant
  - Once all required CRFs have been completed and provided to the SUNRRISE Trial Office, and any data queries resolved
  - Review CRFs and confirm all data featured are accurate
  - Due approximately 3 weeks after the Day 30 assessment is completed BUT it may be preferred to wait until it is requested by the **SUNRRISE** Trial Office, who will only do so after all (if any) query are resolved
- CRFs may include a "PI declaration" section BUT following the implementation of the "Declaration Form for CRF Data", this <u>does not need to be completed on the individual CRFs</u> before sending to the **SUNRRISE** Trial Office
  - This was originally used to document the local PI confirmation that all the data featured on the form are accurate and demonstrate oversight
  - This section has been retain to allow this mode of data sign-off to continue if preferred

Audit and Inspection

- Your sites is subject to audit/inspection by Sponsor
  - Can occur at any time during recruitment and follow-up
  - Investigators are obliged to cooperate in any audits/inspections
- Investigators must tell the Trial Manager immediately if they are being inspected/audited
  - E.g. local audits by R&D

Monitoring

Aspects of the trial that are monitored include:

- Review of site file
  - Fully regulatory documentation present
  - Current protocol, PIS, ICF present
- Consents
  - Copies sent to BCTU for this purpose
  - Sending asap increase the chances of resolving any issues whist the patient is still in hopsital
- AEs/SAEs
- Enrolment and screening logs
- Delegation Logs, CVs & GCP training, trial training
- Source data verification - may involve direct access to patient notes

Types of Monitoring

Central Monitoring

- SUNRRISE Trial Office will:
  - Be in regular contact with the site research team to check on progress and address any queries that they may have
  - Check incoming CRFs for compliance with the protocol, data consistency, missing data and timing
  - Ask sites for missing data or clarification of inconsistencies or discrepancies
  - Protocol compliance via checks on data
  - Ask sites to complete document checklists (e.g. Investigator Site File Checklist)

Monitoring Visits

- On-site monitoring visits may occur if triggered - requires access to medical notes
- Triggers for onsite monitoring visits include but are not limited to:
  - Poor CRF return
  - Poor data quality
  - Low SAE reporting rates
  - Excessive number of participant withdrawals or deviations
- If a monitoring visit is required, the trial office will contact the site to arrange a date for the proposed visit and will provide the site with written confirmation

Deviations and Breaches

Deviations (non-compliances)

- Protocol deviations (including missed or delayed tests or visits) must be reported to the **SUNRRISE** Trial Office as soon as possible
- Note to File to be completed – see CRF completion guidance in ISF
  - Some CRFs allow for non-compliances ice to be documented
    e.g. Randomisation (QoL completion), Wound Assessment (method and timing of assessor)

Serious breaches in GCP or trial protocol

- A serious breach is a breach which is likely to effect to a significant degree:
  - Safety or physical or mental integrity of trial subjects
  - Scientific value of trial
- All trial investigators must promptly notify CI or Sponsor of a serious breach
- Serious breaches reported to REC
- Corrective and preventative action plan (CAPA) prepared and implemented
- Lead to possible suspension from further recruitment

Confidentiality

- **All information collected during course of trial will be kept strictly confidential**
- Trial numbers will be allocated and all data received by co-ordinating centre will be pseudo-anonymised (unless otherwise stated)
- Sites will comply with all aspects of General Data Protection Act 2018 (and subsequence regulations) and operationally this will include:
  - Consent from patients or consultee/representative to record personal details including name, date of birth, address, telephone number, NHS number and hospital number
  - Appropriate storage, restricted access and disposal arrangements for patients personal and clinical details
  - Consent from patients for access to their medical records by responsible individuals from research staff or from regulatory authorities, where it is relevant to trial participation
  - Consent from patients for data collected for trial to be used to evaluate safety and develop new research

Investigator site file (ISF)

- **The Investigator Site File contains the essential documents necessary for the PI and the research team to conduct a trial**
- All centres will be provided with a site file, which is to be stored securely
- Sites are expected to keep the site file up to date e.g. following amendments to the trial or changes to the processes within the study
- Version control document for key documents (protocol, PIS, ICF, CRF etc.) can be found at the front of the site file - **must be kept up to date** and current approved documents used
- The site file will be monitored by site staff and by a representative of Sponsor
  - ISF checklists (see monitoring)
- Records should be handled in accordance with instructions from Sponsor
- If any documents that should be stored in the site file are kept elsewhere, a Note to File should be filed in the relevant section referencing the true location

Investigator site file (ISF)

NO.	SECTION
	Front of File
1	List of Contacts
2	Current and Superseded Trial Protocols
3	Site Initiation and Trial Training Documents
4	Study Personnel
5	Sponsorship, Insurance and Indemnity
6	Ethics Committee and Regulatory Affairs (REC and HRA)
7	R & D
8	Patient Information Sheet and Consent Forms Supply of current PIS, ICF and GCP letter are stored in section 18 (Study-related supplies)
9	Patient Identification Logs and Completed Consent Forms

NO.	SECTION
10	Randomisation Procedure & Eligibility
11	SUNPD & Smith and Nephew
12	Data Collection (Management and Guidelines)
13	Safety / SAE Reporting
14	Monitoring and Audit
15	Interim and Final Reports
16	Correspondence
17	Ad-doc documents
18	Study-Related Supplies
19	CRFs N.B. Version control document is kept at the front of the site file. Please ensure this is up to date.
20	Completed CRFs

Record Retention & Archiving

At end of trial:

- It is the responsibility of the PI to ensure all essential trial documentation and source documents (e.g. signed ICFs, ISF, participants' hospital notes, copies of CRFs etc.) at their site are securely retained for at least 10 years

No documents will be destroyed without prior approval from the SUNRRISE Trial Office on behalf of the Sponsor

- Once permission is given by the Sponsor, documents can be archived in accordance with the sites processes and procedures in an appropriate archive facility
- If the PI leaves after the end of the study, all responsibility for archiving should be transferred to a designated person acceptable to the Sponsor
- Following written authorisation from Sponsor, arrangements for confidential destruction will then be made

SUNRRISE

Thank you

Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 6

- SUNPD supplies
- Other trial supplies

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SUNPD Supplies

SUNRRISE

- Provided free for use in the trial by Smith & Nephew; **PICO™ 7 with 2 dressings**
- SUNRRISE Trial Office will arrange for initial supply prior to site opening
- Sites to monitor stocks and request resupply via the SUNRRISE Trial Office; SUNRRISE@trials.bham.ac.uk

Delivery time:
2-3 working days

- Suggested SUNPD are stored in a marked box in the emergency theatre complex
  - marked "SUNPD for SUNRRISE Trial use only"
  - Labels provided for affix to each kit (shown here)

  - Suggested that research nurse/PI/lead trainee or contact keeps the majority of the dressing stock in a secure office and regularly resupply theatre box
- Please nominate a "SUNPD Contact" - liaise with BCTU

How will dressing stock be stored/managed at your site? Who will do it? How many do you need overall and how many readily accessible?

Other Trial Supplies

Please contact the SUNRRISE Trial Office to request:

- Freepost addressed envelopes or labels
- Labels for patient notes
- Supplies of:
  - PIS and ICF – *electronic and hardcopies*
  - CRF – *electronic and hardcopies*
  - QoL Questionnaire and Patient Diaries – *only hardcopies can be provided due to license restrictions.*
- Any trial documentation - *electronic and hardcopies*

Many documents can be downloaded from our website and/or online ISF repository (get in touch to request access to the repository)

Thank you

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk

SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

Substantial Amendment Number 2 (SA#02)

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Amendment

SUNRRISE

Overall…

- Substantial – REC review required
- Category A – site review required

Amended Documents	Current Version
Protocol	v3.0 (05-Aug-20)
Patient Information Sheets; (Standard & Delayed) and Summary	v3.0 (05-Aug-20)
Patient Consent Forms; (Standard & Delayed)	v3.0 (05-Aug-20)
England & Wales only:	
Consultee Information Sheet	v3.0 (05-Aug-20)
Consultee Declaration Form	v3.0 (05-Aug-20)
Scotland only:	
Legal Representative Information Sheet	v2.0 (05-Aug-20)
Legal Representative Consent Form	v2.0 (05-Aug-20)

Amendment

SUNRRISE

Changes to pathways…

- Wound Assessment at Day 30 can be completed…
  - Remotely (video call) if patient not returning to hospital as part of routine care
  - 30-44 days
- Wound Assessment at Day 7 can be completed…
  - 5-10 day
- Patient Diary return…
  - Patients to be provided with freepost envelope to return Patient Diary direct to Trial Office
  - If assessment completed in-person, diary can still be collected from patients and sent with CRF to Trial Office by sites
  - If competed remotely, remind patients to post diary to Trial Office

These changes have been made to allow to run in the post-COVID-19 era to protect patient and assist sites rouser capacity issues (as detailed in the new COVID-19 section of the protocol)

Amendment

SUNRRISE

Changes to trial design…

- Eligibility criteria…
  - Minor change to reflect change to pathways i.e. remote FU

  "Patients willing and able to ~~attend~~ undergo follow-up at 30 days post-op"
- Sample size…Wound Assessment at Day 7 can be completed…
  - Increased to 840 (additional 210 participants BUT not from UK sites)
  - This will increase power from 80% to 90%
- Australia
  - SUNRRISE is now international
  - Additional participants to increase power will be recruited from AUS
  - Will enhance generalisability of SUNRRISE
- Recruitment targets due to COVID-19 pause…
  - Before; UK = 630, AUS = 210
  - After; UK + AUS = 840

  This will allow the trial to completed as soon as possible

Amendment

SUNRRISE

Clarification of…

- Inclusion of patients with a reasonable chance of laparotomy
  - If the planned operative approach is laparoscopic but there is significant likelihood of converting to open an approach, the patient can be approached and consented
  - If the procedure does not convert to open i.e. there is not a 5cm+ incision at the end of the operation, the patient is not to be randomised
- Requirements of local research team members with regard to… training and wound assessments
  - Training – PI can nominate delegates (e.g. API, lead research nurse) to disseminate study-specific and dressing application training
  - Wound assessment – undertaken by qualified medics or nurses
- Secondary outcome to more accurately define parameters of length of stay
- Safety reporting
  - Events meeting the definition of serious only do not require reporting using the SAE form if the are 1) excluded form expedited reporting or 2) excluded from reporting at all, as already defined in the protocol

Amendment

SUNRRISE

Clarification of…

- Data handling…
  - Now refers to Data Protection Act 2018 rather than GDPR
  - Archiving period reduced to 10 years
  - Primary outcome data for participant who discontinue will be obtain form medical notes where possible
- Statistical analysis…
  - Specific methods that will be used , such as “mixed methods” and “mix effects”
  - Sub-group analysis by country (UK and AUS) added
- Health economics analysis and what it will involve

Amendment

SUNRRISE

Other changes to protocol…

- Minor clarification and suggestions of pathways and processes
  - Use of intervention; other SUNPD in control arm, application following a return to theatre
  - Use of QoL booklet whist a participant remain an inpatient
- Update oversight committee members
- Update to sponsor contact and details
- Minor administrative changes e.g. reference numbers
- Recontextualisation of feasibility phase following its completion
- Minor changes relating to typographical errors, corrections to gramma and consistent/correct use of terminology

Amendment

SUNRRISE

Other changes to other documents…

The changes to the information sheets and consent/declarations in addition to those already discussed, and that are not administrative are include:

- Informed Consent Forms (Standard & Delayed)
  - Inclusion of clause for the "unlikely event of loss of capacity" that data can be used for the sole purposes for which consent was sought
- Information sheets
  - Typographical and phasing corrections

Outside of this amendment the CRFs have also been updated where necessary to reflect the changes to the protocol (e.g. FU) and also to collect basic COIVD-19 data.