

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

Site-specific Training Presentation

Substantial Amendment Number 2 (SA#02)













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 NIHF or the Department of Health and Social Care.



Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Amendment



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



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)

Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Amendment



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

e Slide 4

Amendment



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 <u>procedure does not convert to open</u> i.e. there is not a 5cm+ incision at the end of the operation, <u>the patient is not to be randomised</u>
- 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

Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Jilue 3

Amendment



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



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

Slide 7

Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Amendment



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 <u>loss</u> 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.





The following provides a brief overview of the trial to refresh knowledge on what SUNRRISE entails

Study-specific Training - SA#02 v1.0 (14-Sep-2020)



Trial Overview



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



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

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
 - systemic fever (>38°C)
 - Heat



Online training

diagnosis of SSI

module for

https://bcturedcap.bham.ac.uk/surve ys/?s=DFPM7YMKRJ

Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Trial Overview



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

Trial Schema: Detailed - Baseline

SUNRRISE

Summary of trial events and activities at baseline





Study-specific Training - SA#02 v1.0 (14-Sep-2020)

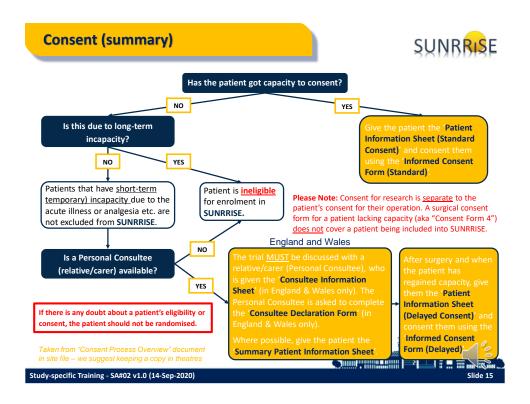
Patient Identification

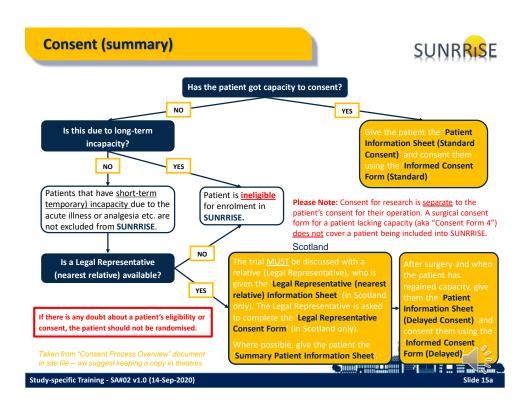


- Potential participants will likely be identified by either a consultant or trainee surgeon once the decision to take them to theatre has been made
- □ Patients will be approached by a member of the research team this member of the research team may be either a member of the clinical team or a research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







Patient Eligibility



INCLUSION CRITERIA

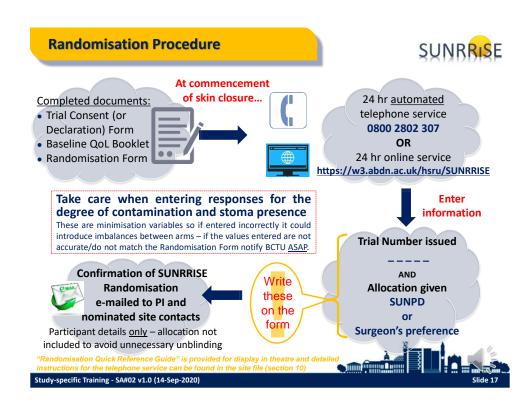
- ☑ Patients undergoing emergency (non-elective) laparotomy
- ✓ Procedures with an incision of at least 5cm
- ✓ Operations where the skin is closed primarily
- ✓ Patients aged at least 16 years
- Patients able to provide written informed consent, or consultee provide assent (declaration) if a patient 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

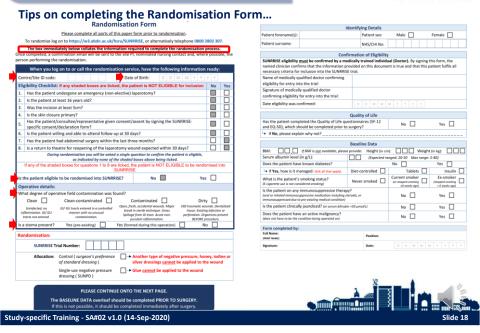
Prior to randomisation, eligibility must be confirmed by a medically qualified doctor with access to and a full understanding of the potential participant's medical history who has been appropriately delegated the duty on SUNRRISE Site Signature and Delegation Log.

Slide 16



Randomisation Procedure





Intervention



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

Size (cm) 20 x 10 30 x 10 40 x 10

□ 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

- Kept with patient in case dressing change required
- If applied, ideally by research team member trained of in application of SUNPD
- Remain in place until Day 7 assessment or discharge
 - > Patients **not** to be discharged with SUNPD

Retain second dressing if unused

Can be used as additional dressings if more than 2-are needed for other SUNRRISE participants

Study-specific Training - SA#02 v1.0 (14-Sep-2020)



Pad size (cm) 15 x 5.6 25 x 5.6 35 x 5.6

Intervention



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

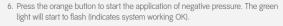
Peel off the first release handle and place the dressing centrally over the wound. The port should be uppermost from the wound.

Remove the other two handles and smooth the dressing around the wound to prevent creasing.

Press

4. Insert the batteries into the device.







- 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



B Dressing requires change - port may



C Dressing requires change - absorben



Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Follow Up

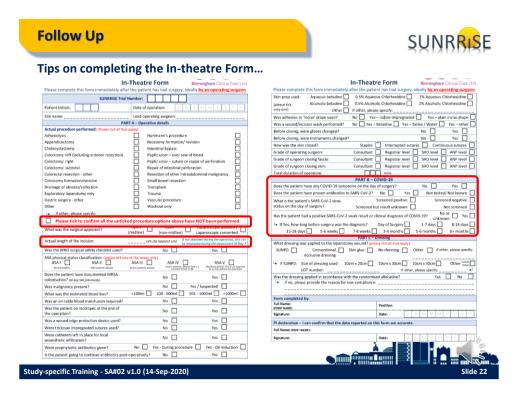


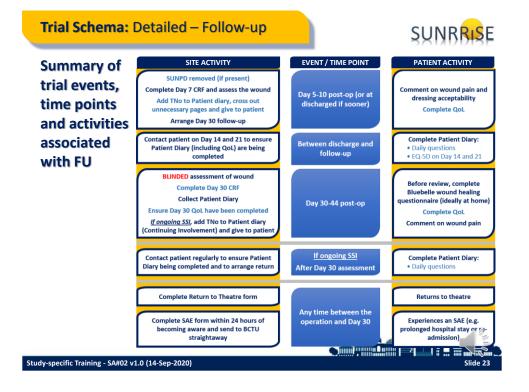
Time point	Activity	CRF
Immediately post-op		In-theatre Form

- 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







Health-related Quality of Life



What	When	How	To note
EQ-5D & SF-12	Post-consent & Pre-op	QoL Booklet	If not complete pre-op, do <u>not</u> complete post-op
EQ-5D & SF-12	Day 7 (-2/+3)	QoL Booklet ^o 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 ^o or Patient Diary	Call patient weekly (if discharged) to check if any problems
EQ-5D & SF-12	Day 30 (+14)	QoL Booklet ^o or Patient Diary	
WHQ	Day 30*	Patient Diary	Completed by patient on day of Day 30 assessment <u>independently</u>
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



Study-specific Training - SA#02 v1.0 (14-Sep-2020)

Follow Up



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 as Should not be earlier Should not be letter to	than 5 days post-op UNLESS co	ompleted on discharge

- Should not be <u>later</u> 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 <u>from index operation to date of assessment</u>; 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

Study-specific Training - SA#02 v1.0 (14-Sep-2020)



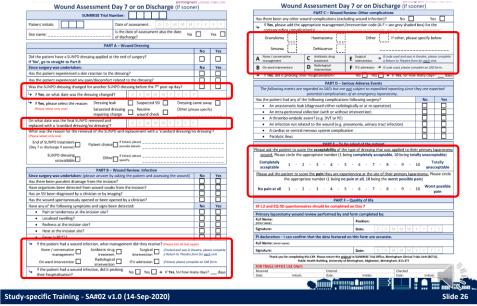


lide 25

Follow Up



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



Follow Up



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

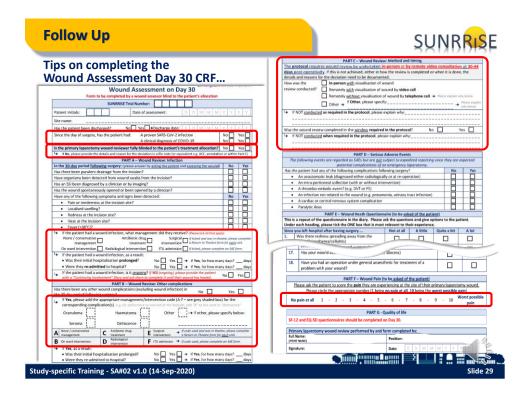
Study-specific Training - SA#02 v1.0 (14-Sep-2020)

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

Follow Up



CRF Time point **Activity** Wound review by assessor 30-44 days post-op Wound Assessment Day 30 **BLIND** to allocation ☐ 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 Study-specific Training - SA#02 v1.0 (14-Sep-2020)





Thank you

Please remember to document your training:

- Online using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- ☐ <u>Hardcopy</u> 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

