SUNRRISE

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

Site-specific Training Presentation

PART 4

- Safety reporting

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

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Safety Reporting

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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

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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

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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

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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

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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

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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…

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