

SITE ACTIVITY

Given PIS

Contact Research Team

Eligibility confirmed and consent taken

Give QoL (EQ-5D & SF-12) to patient

Begin to complete Randomisation form

Add *actual* operative details to Randomisation form

RANDOMISE

Apply SUNPD or Surgeon's preference of dressing (as allocated)

Complete In-Theatre form, ideally by operating surgeon

Add trial number to consent and QoL

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

Contact patient on Day 14 and 21 to ensure Patient Diary (including QoL) are being completed

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

EVENT / TIME POINT

Patient admitted

Decision to operate

- Emergency laparotomy
- Primary skin closure of ≥5cm incision

PATIENT ACTIVITY

Consider participation

Give consent

Complete QoL (EQ-5D & SF-12)

Taken to theatre

Skin closure commenced

End of operation

Immediately post-op

Day 5-10 post-op (or at discharged if sooner)

Between discharge and follow-up

Day 30-44 post-op

Comment on wound pain and dressing acceptability

Complete QoL

Complete Patient Diary:

- Daily questions
- EQ-5D on Day 14 and 21

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

Complete SAE form within 24 hours of becoming aware and send to BCTU straightaway

Any time between the operation and Day 30

Returns to theatre

Experiences an SAE (e.g. prolonged hospital stay or readmission)

