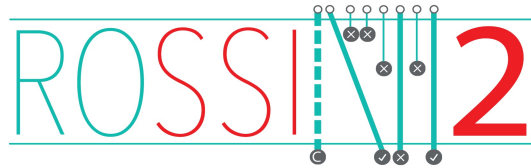


Initials: Site ID:

UNIVERSITY OF
BIRMINGHAM



RANDOMISATION FORM

Please complete all parts of this form prior to randomisation.

Date of Birth: e.g. 31-JAN-2017 D D - M M M - Y Y Y Y

PART A - Eligibility Criteria

If any shaded answers are ticked, the patient is **NOT ELIGIBLE** to be randomised into ROSSINI 2.

- | | |
|---|--|
| 1. Is the patient undergoing an abdominal operation? (this may include colorectal, hepatobiliary, upper GI, urological, vascular or gynaecological) | <input type="radio"/> No <input type="radio"/> Yes |
| 2. Does the procedure have a planned incision of at least 5cm? | <input type="radio"/> No <input type="radio"/> Yes |
| 3. Is the patient aged 16 years or older? | <input type="radio"/> No <input type="radio"/> Yes |
| 4. Has the patient given valid written informed consent? | <input type="radio"/> No <input type="radio"/> Yes |
| 5. Is the patient able and willing to undergo a wound assessment at day 30-37 after surgery? | <input type="radio"/> No <input type="radio"/> Yes |
| 6. Has the patient had a previous laparotomy within the past three months? | <input type="radio"/> No <input type="radio"/> Yes |
| 7. Is the patient known to be pregnant or currently breast feeding? | <input type="radio"/> No <input type="radio"/> Yes |
| 8. Will this patient have a wound left open? | <input type="radio"/> No <input type="radio"/> Yes |

If **any** of the answers to questions 9 and 10 are 'Yes' then the patient will not be randomised into the arms described in **bold**. If **all** of the answers to the questions below are 'Yes' then the patient is not eligible.

- | | |
|--|--|
| 9. Does the patient have a documented allergy/ intolerance to chlorhexidine? (If Yes, the patient will not be randomised to arms containing SKIN PREP) | <input type="radio"/> No <input type="radio"/> Yes |
| 10. Does the patient have end-stage renal failure (ESRF) or a documented allergy/ intolerance to gentamicin or collagen? (If Yes, the patient will not be randomised to arms containing the SPONGE). | <input type="radio"/> No <input type="radio"/> Yes |

PART B - Confirmation of Eligibility

ROSSINI 2 eligibility must be confirmed by an appropriately delegated member of the local research team. By signing this form, this person confirms that the information provided on this document is true and that this patient fulfils all necessary criteria for inclusion in the ROSSINI 2 Trial.

Is the patient eligible to be randomised into ROSSINI 2? No Yes

Name of person confirming eligibility for entry into the trial? *(This person must be on the Delegation of Duties Log)*

Signature of person confirming eligibility for entry into the trial? *(This person must be on the Delegation of Duties Log)*

Date eligibility was confirmed: e.g. 31-JAN-2017 D D - M M M - Y Y Y Y

Initials: Site ID:

PART C - Operative Predictions

Is this surgery: *(Please tick one)*

- Elective (planned admission)
 Emergency (unplanned admission)

Will this surgery be: *(Please tick one)*

- Open
 Laparoscopic/ Laparoscopic Assisted

What is the predicted surgical contamination level at time of randomisation? *(See definitions below) (Please tick one)*

- Clean Clean - Contaminated Contaminated Dirty

At the end of the operation, do you predict that the patient will have a stoma? *(Please tick one)*

- No Yes (pre-existing) Yes (formed during this operation)

You are now ready to randomise the patient into the ROSSINI 2 Trial.

PART D - Randomisation

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

To randomise, please log on to <https://w3.abdn.ac.uk/hsru/ROSSINI2> or alternatively telephone **0800 2802 307 / 01224 27 3661**.

Date of Randomisation: *e.g. 31-JAN-2017* - -

The patient has been randomised to: *(Please tick one)*

- A. None (Control)
 B. SKIN PREP
 D. SPONGE
 F. SKIN PREP and SPONGE

ROSSINI 2 Trial Number: *(TRIAL ID)*

Name of person randomising:

Once completed, a (blinded) confirmation email will be sent to the PI and Research Team. An (unblinded) confirmation email will be sent to the person performing the randomisation.

Contamination Levels

Clean (Elective) - Uninfected, no inflammation & GI/ GI tracts not entered. *Example procedures - Hernia repair (no bowel resection anticipated), Adhesiolysis*

Clean-contaminated (Elective/ Emergency) - GI/ GI tracts entered in a controlled manner with no unusual contamination. *Example procedures - Appendicectomy (non-inflamed appendix anticipated), Cholecystectomy (no bile spillage anticipated), Bowel resection (no gross spillage of faeces anticipated), Caesarean section*

Contaminated (Elective/ Emergency) - Open, fresh, accidental wounds. Major break in sterile technique. Gross spillage of contents of GI/ GU tracts. Acute non-purulent inflammation. *Example procedures - Appendicectomy (inflamed, non-perforated appendix anticipated), Laparotomy for infarcted or necrotic bowel (no perforation anticipated)*

Dirty (Emergency) - Old traumatic wounds. Devitalized tissue. Exiting infection or perforation. Organisms present BEFORE procedure. *Example procedures - Laparotomy for perforated duodenal ulcer, Hartmann's procedure for perforated sigmoid colon, Old traumatic wounds with devitalized tissue.*

Completed By

Full Name: *(PRINT NAME)*

Signature:

Position:

Date: *e.g. 31-JAN-2017* - -

Thank you for completing this CRF. You are now required to transcribe this information onto REDCap (<https://bctu-redcap.bham.ac.uk/>). This CRF can be used as Source Documentation and filed in the patient's records.