ISRCTN95680782 https://doi.org/10.1186/ISRCTN95680782

The ROSSINI-Platform Trial: A basket factorial multi-arm multi-stage (MAMS) platform randomised controlled trial (RCT) to evaluate the use of multiple interventions to reduce surgical site infection SSI across several types of surgery

Submission date 17/03/2026	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 12/05/2026	**Overall study status** Ongoing	
Last Edited 03/06/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

Surgical site infections are wounds that become infected after an operation. They can cause pain, delay recovery and sometimes lead to serious health problems. Different types of surgery have different risks, and current infectionprevention guidance is often very general. The ROSSINIPlatform study aims to find out which specific infectionprevention techniques work best for different types of surgery. The study will test several methods already used in some hospitals to see whether they reduce infection rates within 30 days after surgery. It will also look at patients' quality of life, hospital stay length and whether the methods offer good value for money.

Who can participate?

Adults aged 18 to 120 years who are having certain types of surgery may be invited to join. The study includes six surgical areas: vascular groin surgery, lower limb amputation, breast surgery, cardiac surgery, caesarean section and neurosurgery. Participants need to be able to give consent (or have a representative do so), and need to be able to take part in followup by email or telephone. People who have already taken part in the study in the previous 90 days cannot join again.

What does the study involve?

If a patient agrees to take part, they will have surgery as planned, but they may also receive one or more infectionprevention methods chosen for their type of surgery. These may include changes in how the wound is cleaned, how dressings are applied or how surgical tools are used. All the methods being tested are already used safely in some hospitals. Patients will be randomly assigned to receive or not receive each method. After the operation, participants will

be followed for up to 30 days to check for infection and for up to 90 days for other outcomes. Followup will take place by phone or email, along with a review of hospital records.

What are the possible benefits and risks of participating?
Taking part may reduce the chance of getting a wound infection, although this cannot be guaranteed. The information collected will help improve infectionprevention guidance for future patients. The study has been assessed as no higher risk than standard medical care. All the tested methods are already approved for use in the United Kingdom and are not known to cause harm. They should not make the operation longer or more difficult. As with any clinical trial, there is a small chance of unexpected side effects, but the risk is considered low.

Where is the study run from?
The study is run from the Birmingham Clinical Trials Unit and will take place in around 100 NHS hospitals across England.

When is the study starting and how long is it expected to run for?
May 2026 to December 2029.

Who is funding the study?
National Institute for Health and Care Research (UK).

Who is the main contact?
ROSSINIPlatform Trial Team, rossini-platform@trials.bham.ac.uk

Contact information

Type(s)
Scientific, Public

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None - ROSSINI- Platform Trial Team

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1009318

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59790

Study information

Scientific Title
The ROSSINI-Platform Trial: A basket factorial multi-arm multi-stage (MAMS) platform randomised controlled trial (RCT) to evaluate the use of multiple interventions to reduce surgical site infection SSI across several types of surgery

Acronym
ROSSINI-Platform

Study objectives
The aim of ROSSINI-Platform is to investigate the clinical and cost effectiveness of several peri-operative interventions in reducing SSI rates in patients undergoing surgery across six specialties: vascular groin, lower leg amputation, breast, cardiac surgery, obstetrics and neurosurgery. The primary objective is to determine if specific peri-operative interventions, used alone or in combination, result in decreased rates of SSI within 30-days post-operation in patients undergoing surgery across six surgical specialties: vascular groin, LLA, breast, cardiac, obstetrics, and neurosurgery.
The platform incudes an internal pilot with platform, pillar and intervention level objectives and outcomes. Due to space limitations, these are detailed within the master protocol and the pillar specific protocols.

Secondary Objectives:
Do the peri-operative interventions:
1. Improve quality of life (QoL) up to 30 days post-surgery?
2. Reduce the rate of mortality up to 90-days post-surgery?
3. Reduce the risks of wound complications up to 30 days post-surgery?
4. Have an acceptable safety profile?
5. Reduce the length of stay in hospital?
6. Reduce the risk of wound complication related hospital re-admissions within 30 and 90 days post-surgery?
7. Reduce the risk of wound reopening and/ or re-operations within 90 days post-surgery?

Exploratory Objectives:
Is there a difference in intervention effect depending on participant co-morbidities (e.g. diabetes, smoking, body mass index (BMI)), duration of operation and operative technique used?

Economic aims and objectives
The health economic evaluation will assess the cost-effectiveness of the compared interventions

from an NHS and personal services perspective for patients undergoing surgery in each of the pillars.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 16/03/2026, To be confirmed (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; a@a), ref: 26/SS/0038

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Basket factorial multi-arm multi-stage (MAMS) platform randomised controlled trial (RCT)

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Prevention of surgical site infection in 6 surgical specialities: obstetrics: caesarean section; neurosurgery; vascular groin; vascular amputation; cardiac; breast

Interventions
Individual pillars have prioritised three specific peri-operative interventions for initial testing based on: (1) evidence of potential clinical effectiveness, (2) patient acceptability and (3) clinician equipoise within their clinical area. Each individual intervention will be compared against those participants not allocated to receive the intervention. See below a list of interventions used in each pillar
Neurosurgery Pillar: Intervention 1: Topical Vancomycin powder under scalp flap
Once the muscle and/or galea has been closed but prior to skin closure, the vancomycin powder (500mg) will be placed topically on the wound edges for the intervention arm. It will be spread out evenly across the length of the wound and a swab may be used to pat it down into the wound. The skin will then be closed in the standard fashion. In the standard care arm no powder will be used and the skin will be closed in the standard fashion.
Neurosurgery Pillar Intervention 2: Bone flap stored in betadine.
Once the craniotomy has been performed and the bone flap lifted off, it will be put into a bowl /dish and submerged in either saline or aqueous betadine (as per randomisation allocation). It will remain in this fluid for the rest of the operation until the surgeon is ready to re-implant the bone flap at which point it will be removed to enable securing of screws/mini-plates and placed

back into the participant.
Neurosurgery Pillar: Intervention 3: Wound irrigation prior to closure
Once the bone flap has been replaced and secured and the surgeon is ready to start closing the muscle/superficial layers, then a large volume wash of a minimum of 1L of warm saline will be used to irrigate the wound. In the standard practice arm, the surgeon can choose to wash the wound at this stage with as much or as little saline as per their standard practice and this does not need to be measured.
Cardiac Pillar: Intervention 1: Glove and Instrument change prior to wound closure
The surgical team (surgeons, scrub nurse, surgical care practitioner etc.) should change gloves and use the clean instruments before handling the sternal wires or the wound edges to facilitate closure.
Cardiac Pillar: Intervention 2: Topical gentamicin-impregnated collagen matrix between sternal edges prior to wound closure.
Gentamicin-impregnated collagen matrix left within wound prior to closure, by a member of the surgical team.
Cardiac Pillar: Intervention 3: Closed incision negative pressure wound therapy.
For patients randomised to closed incision Negative-Pressure Wound Therapy , this should be applied at the end of the operation following skin closure as per the manufacturer's instructions.
Obstetric Pillar: Intervention 1: Vaginal cleansing prior to caesarean section
The intervention will be provided at the time of catheter insertion under anaesthesia, this will be carried out by the surgeon or nurse/midwife.
Obstetric Pillar: Intervention 2: Prophylactic antibiotics after umbilical cord clamping
This will be delivered by the anaesthetist during the participants surgery after the clamping of the umbilical cord.
Obstetric Pillar: Intervention 3: Glove and instrument change for closure
This will be performed by the surgical team during the operation after delivery of the placenta.
BREAST Pillar: Intervention 1: Dialkylcarbomoyl chloride (DACC)-coated dressings
The dressing should be applied as per normal practice at the end of the operation, whilst in surgery, once the wound has been closed with sutures, and the skin cleaned and dried. No other 'dressings' should be used (e.g. glue/use of steristrips). The dressing should remain in place for up to 7 days. If it becomes saturated and/or peels off, a further DACC dressing can be re applied if needed.
Breast pillar: Intervention 2: Wound irrigation with Granudacynâ prior to closure
The wound and cavity should be irrigated with Granudacynâ prior to closure of the breast wound with surgeon choice of sutures. Irrigation of the wound should be performed as per usual practice e.g. with a sterile jug, syringe or bulb syringe. Suction can be used/not depending on usual practice.
BREAST Pillar: Intervention 3: Prophylactic antibiotics at induction
A single dose of intravenous antibiotics should be administered at the induction of anaesthesia, in surgery. Antibiotic choice at induction of anaesthesia will be as per breast unit policy, but type, dose and route will be recorded. As Staphylococcus aureus is the commonest cause of breast SSI, most prophylactic antibiotic policies are likely to include flucloxacillin or co-amoxiclav, with teicoplanin, gentamycin or clindamycin being used if patients are penicillin allergic.
Vascular Groin: Intervention 1: Hair Removal: Waxing/epilation.
To be carried out by an appropriately trained individual using manufacturers guidance for the intervention of choice. This should be performed perioperatively, usually once the patient has been anaesthetised and immediately prior to skin preparation.
Vascular Groin: Intervention 2: Glove & instrument change prior to closure.
Following completion of the arterial procedure, before any layers of the groin wound are closed surgical teams should change; gloves of the operating surgeons, assistant surgeons, and scrub staff (or outer gloves if double gloved), and instruments (a sterile set of instruments should be

used for all layers of groin closure including; a needle holder, forceps, and scissors).
Vascular Groin: Intervention 3: Incisional negative pressure wound therapy
This should be applied by an appropriately trained person (usually surgeon or assistant). Any adjuncts used to improve the fidelity of the device are allowed, as long as they are approved for use by the manufacturer of the negative pressure device and used in accordance with guidance of application (such as skin sealants or skin adhesives). The device should be applied in theatre, under sterile conditions.
Vascular LLA (Lower limb amputation) Intervention 1: Double skin preparation with 2% alcoholic chlorhexidine followed by an alcoholic iodine solution
Any 2% alcoholic chlorhexidine applicators/solutions are permitted for patients randomised to this intervention and can be based on the operating surgeon’s preference.
Vascular LLA (Lower limb amputation) Intervention 2: Subcuticular continuous skin closure with an absorbable suture
This intervention describes a method of skin closure chosen by the surgeon, whereby an absorbable suture placed entirely within the subcuticular layer is used to approximate the skin edges.
Vascular LLA (Lower limb amputation) Intervention 3: Closed incision negative pressure wound
This will be the surgeon's choice. This intervention describes the application of a dressing and device combination that aims to deliver continuous negative pressure therapy to a closed wound at the end of surgery. After closing, cleaning, and drying the skin, the dressing and device combination will be applied in theatre.

Randomisation
Randomisation will be provided by Birmingham Clinical Trials Unit (BCTU) using a secure online system, thereby ensuring allocation concealment. Unique log-in usernames will be provided to those who wish to use the online system and who have been delegated the role of randomising participants into the trial as detailed on the Site Signature and Delegation Log.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
azithromycin, vancomycin

Primary outcome(s)
The primary outcome is SSI within 30 days of surgery, as defined according to a modified 2017 Centers for Disease Control (CDC) and Prevention criteria. Whilst several systems exist to define SSI, the internationally recognised CDC definitions are the current gold standard for SSI assessment and have been used in a number of multicentre randomised trials.
The following CDC definition will be used in ROSSINI-Platform to identify deep incisional or superficial incisional SSIs:
1. The infection must occur within 30-days of the index operation
AND
2. The infection must involve the skin, subcutaneous, muscular or fascial layers of the incision
AND
3. The patient must have at least one of the following:
• Purulent drainage from the incision
OR

• Wound opened spontaneously or deliberately by a clinician
AND the patient has at least one of: pain or tenderness; localised swelling; erythema or heat; fever (>38°C).
OR
• Organisms are cultured from a culture taken from the wound using an aseptic technique
OR
• Diagnosis of SSI by a clinician or on imaging
Surgical site infection in ROSSINI-Platform encompasses both superficial and deep incisional wound infections. In practice, a deep incisional infection will manifest alongside a superficial one and can be viewed as a more severe subset of the latter. We will not seek to differentiate between deep and superficial SSI as our interventions seek to prevent both.

The primary outcome is measured at 30 days post surgery

Key secondary outcome(s)
30-day and 90-day postoperative mortality rate (POMR).
30-day postoperative worst wound complication (Clavien-Dindo classification for vascular groin, LLA, breast, cardiac and obstetrics; Landriel-Ibanez33 classification for neurosurgery).
Risk of wound or intervention only related Serious Adverse Events up to 30 and 90 days post-surgery.
Length of hospital stay after surgery as measured from the date of surgery to the date fit for discharge from primary site collected via hospital records.
Risk of hospital re-admission for wound related complications within 30 and 90 days post-surgery.
Risk of wound reopening and/or re-operations within 30 and 90 days post-surgery.
Preference-based Quality of Life (QoL EQ-5D-5L) collected at Baseline, Day of Discharge and weekly until Day 30 post-surgery via the CDWH.
Cost effectiveness (Resource Use Questionnaire; RUQ).

• 30-day and 90-day postoperative mortality rate (POMR).
• 30-day postoperative worst wound complication rate
• Wound or intervention only related Serious Adverse Events up to 30 and 90 days post-operatively.
• Length of hospital stay after surgery as measured from the date of surgery to the date fit for discharge from primary site collected via hospital records.
• Hospital re-admission for wound related complications within 30 and 90 days post-discharge.
• Risk ogf wound reopening and/or re-operations within 30 and 90 days post operation.
• Preference-based Quality of Life (QoL EQ-5D-5L) collected at Baseline, Day of Discharge and weekly

Completion date
31/12/2029

Eligibility

Key inclusion criteria
As there are 6 surgical specialities, there are platform level and pillar-specific level eligibility criteria.
The platform level criteria are listed below.
1. Patients undergoing vascular groin, LLA, breast, cardiac, obstetric, vascular groin or neurosurgery at a ROSSINI-Platform participating hospital.

2. Patients (or via support from family member/ carer etc) with an email address and/or telephone number who are able and willing to provide follow-up through the CDWH
3. Able to give informed consent, with interpreters where necessary OR consultee /representative provides assent/consent if a patient temporarily lacks capacity

The pillar-specific eligibility are within each pillar specific protocol.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Platform level exclusion criteria:
1. Previous participation in any Pillar of ROSSINI-Platform within the last 90 days.

There are pillar-specific exclusion criteria listed within each protocol (not enough space to detail them all here).

Date of first enrolment
31/05/2026

Date of final enrolment
31/05/2029

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
-
-

England
-

Sponsor information

Organisation
Birmingham Clinical Trials Unit

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The final dataset will be available to members of the ETMG and others who need access to the data to undertake the final analyses. This will include staff at both UoB and the UCL-MRC. Requests for data generated during this study will be considered by BCTU. Data will typically be available six months after the primary publication unless it is not possible to share the data (for example: the trial results are to be used as part of a regulatory submission, the release of the data is subject to the approval of a third party who withholds their consent, or BCTU is not the controller of the data).
Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the CI and, where appropriate (or in absence of the CI) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent TSC.

A formal Data Sharing Agreement (DSA) may be required between respective organisations once release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers transfer of participant identifiable information. Any data transfer will use a secure and encrypted method.

IPD sharing plan summary

Available on request