ROSSINI-PLATFORM TRIAL

Pillar-Specific Protocol

VASCULAR GROIN

A 'Basket Factorial MAMS' Platform Trial in Surgical Site Infection

This protocol has regard for the HRA guidance and is compliant with the SPIRIT guidelines (2025)

Version Number: 1.0

Version Date: 05-Jan-2026

VASCULAR GROIN PILLAR SPECIFIC PROTOCOL DEVELOPMENT

Protocol amendments

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment

Funding and support in kind	
Funder(s)/Supporting Organisations	**Financial and non-financial support given:**
National Institute of Health and Care Research (NIHR)	Financial, Investigator led grant
Funding scheme	NIHR Health Technology Assessment (HTA) Programme
Funder's reference number	NIHR163832
The funder of the trial will have no role in the trial design, data collection, data analysis or data interpretation, or in the writing of the final report; and the decision to submit the report for publication. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.	

SUPPLIERS
Provision of intervention

PROTOCOL SIGN OFF

Pillar Lead for Vascular Groin - Signature Page

I, the Pillar Lead, confirm that I have read and agree with the following protocol, and that I will conduct the trial in compliance with the version of this protocol approved by the REC and any other responsible organisations.

I agree to ensure that the information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given; and that any discrepancies from the study as stated in this and any subsequent approved protocol will be explained.

Trial name:	ROSSINI-Platform (VASCULAR GROIN Pillar)
Protocol version number:	Version: __ __
Protocol version date:	__ __/__ __ __/__ __ __ __
Pillar lead name:	Mr M A Popplewell
Signature and date:	_____ __ __/__ __ __/__ __ __ __

Sponsor statement

By signing the IRAS form for this trial, University of Birmingham, acting as sponsor, confirm approval of this protocol.

Compliance statement

This protocol describes the VASCULAR GROIN Pillar within the ROSSINI-Platform trial only. The protocol should not be used as a guide for the treatment of patients not taking part in the Vascular Groin Pillar of the ROSSINI-Platform trial.

The trial will be conducted in compliance with the approved protocol, the UK Policy Framework for Health and Social Care Research, the Medicines for Human Use (Clinical Trials) Regulations 2004, Data Protection Act 2018 and the Principles of Good Clinical Practice (GCP) as set out in the UK Statutory Instrument (2004/1031) and Mental Capacity Act 2005, and subsequent amendments thereof. Every care has been taken in the drafting of this protocol, but future amendments may be necessary, which will receive the required approvals prior to implementation.

Principal Investigator (PI) signature page

As Principal Investigator, I confirm that the following protocol has been agreed and accepted, and that I will conduct the trial in compliance with the approved protocol where this does not compromise participant safety.

I agree to ensure that the information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

Trial name:	ROSSINI-Platform (VASCULAR GROIN Pillar)
Protocol version number:	Version: __ __
Protocol version date:	__ __ /__ __ __ /__ __ __ __
PI name:	
Name of Site:	
Signature and date:	_____ __ __ /__ __ __ /__ __ __ __

ADMINISTRATIVE INFORMATION

Trial office contact details	
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Randomisation website	< tbc >
Trial website	< tbc >
Trial social media	< tbc >

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TBC	PPI Representative

ABBREVIATIONS

Abbreviation	Term
BCTU	Birmingham Clinical Trials Unit
CDWH	Centralised Digital Wound Hub
CI	Chief Investigator
ciNPWT	Closed Incision Negative Pressure Wound Therapy
eCRF	Electronic Case Report Form
ETMG	Executive Trial Management Group
GCP	Good Clinical Practice
GP	General Practice
HRA	Health Research Authority
ISF	Investigator Site File
MAMS	Multi Arm Multi Stage
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PI	Principal Investigator
PSP	Pillar Specific Protocol
RAG	Red-Amber-Green
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RSI	Reference Safety Information
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SSI	Surgical Site infection

TAVI	Transcatheter Aortic Valve Implantation
TSC	Trial Steering Committee
UK	United Kingdom
WHO	World Health Organization

ROSSINI PLATFORM: VASCULAR GROIN PILLAR TRIAL SUMMARY

INTERVENTIONS	1. Hair Removal: Epilation vs. Skin clipper 2. Instrument & glove change prior to closure vs. standard practice 3. Closed incision negative pressure wound therapy vs. standard practice
PARTICIPANT POPULATION AND SAMPLE SIZE	Estimated 7,000 groin incisions per year Sample size 3,648 participants
PILLAR-SPECIFIC ELIGIBILITY CRITERIA **INCLUSIONS**	**Inclusion criteria;** • Patients aged 18 years or older undergoing an emergency or elective groin incision(s) for arterial intervention including endarterectomy, embolectomy, thrombectomy, bypass, repair of (non-infected) traumatic injury (i.e. iatrogenic pseudoaneurysm) or exposure for an endovascular procedure within anatomical boundaries of the femoral triangle. This can include incisions that extend onto the abdomen or down the leg. • Able to provide informed consent with the use of appropriate translation facilities if appropriate.
PILLAR-SPECIFIC ELIGIBILITY CRITERIA **EXCLUSIONS**	**Exclusion criteria;** • Groin surgery for infective complications, e.g. the groin is already infected (pseudoaneurysm, explanation of infected prosthetic material etc.) • Groin exposure for venous access only without arterial exposure or intervention • Groin exposure performed for cardiac procedures, e.g. Transcatheter Aortic Valve Implantation (TAVI); access for cardiac bypass • Known allergy to any of the interventions where appropriate: ○ **For Intervention 1: Epilation** ▪ Frail/fragile skin that is liable to tearing ▪ Severe infection or intertrigo ▪ Allergy to waxing strips (epilators can be used if available in this circumstance) ○ **For intervention 3 closed incision negative pressure wound therapy (ciNPWT)** ▪ To material within adhesive dressing used to deliver ciNPWT ▪ Frail/fragile skin that is liable to tearing • Patients who have undergone a groin incision in the previous 90 days

PILLAR SAMPLE SIZE	3,648
TIMELINES	Up to 50 months of recruitment.

TRIAL SCHEMA

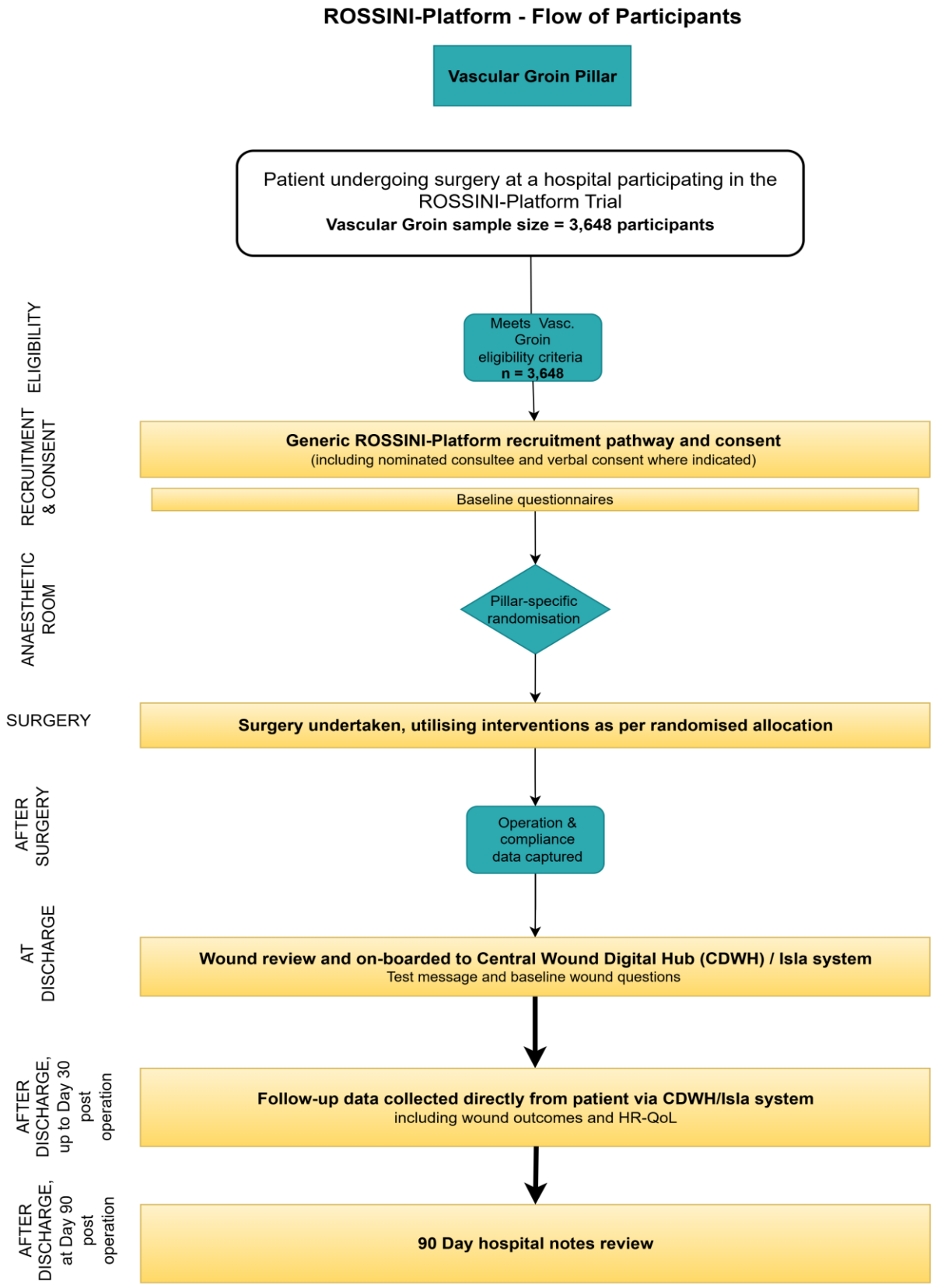

TABLE OF CONTENTS

1. PILLAR SPECIFIC PROTOCOL STRUCTURE

The structure of this protocol is different to that used for conventional trials because this trial is highly adaptive and the description of these adaptations is better understood and specified using a 'modular' protocol design. While, all adaptations are pre-specified (the dropping or addition of interventions/pillars), the structure of the protocol is designed to allow the trial to evolve over time, for example by the introduction of new interventions or pillars or both.

The protocol has multiple modules comprising the ROSSINI-Platform Master Protocol (overview and design features of the study) and multiple Pillar Specific Protocols (PSP) (detailing all interventions currently studied in each pillar).

The Master Protocol contains all information that is generic to the trial, irrespective of the pillars or interventions that are being tested. The Master Protocol may be amended but it is anticipated that such amendments will be infrequent. The Master Protocol does not contain information about the intervention(s) within each pillar as one of the trial adaptations is the change of interventions over time.

Information about interventions, within each pillar, is covered in a PSP. These PSPs are anticipated to change over time, with removal and addition of options within an existing pillar. Each substantial modification to a PSP will require regulatory approval.

The Master Protocol does not contain detailed information about the statistical analysis, but this information is contained within the Statistical Analysis Plan (SAP).

2. BACKGROUND AND RATIONALE

2.1 Pillar definition

This is a Pillar within the ROSSINI-Platform Trial to test the effectiveness of specific peri-operative interventions to prevent Surgical Site Infections (SSI) in adult patients who are undergoing a groin incision for access to the femoral artery by a vascular surgeon.

2.2 Pillar-specific background

Impact of SSI

The groin is the commonest surgical site in vascular surgery and allows access to the lower limb arterial tree as well as the major abdominal and pelvic vessels. Operations are often performed in comorbid and elderly patients and SSI is common, causing significant morbidity including; longer hospital stay, slower recovery, and more district nurse, General Practice (GP) and hospital visits. Vascular groin SSI can also result in loss of limb and/or life.

Baseline SSI rates

A large systematic review and meta-analysis of 3,747 patients undergoing 4,130 vascular groin incisions reported an SSI rate of 17.7% per incision (1). The constituent studies were mostly randomsied controlled trials (RCTs) in which SSI was the primary endpoint – as such we feel this rate is stable and robust.

The systematic review showed a benefit for closed incision negative pressure wound therapy (ciNPWT) and possibly subcuticular suturing (versus transdermal sutures or skin clips). A large multicentre, mostly United Kingdom (UK) prospective study, undertaken by members of this pillar that documented the rate of groin wound SSI in 1,337 incisions, reporting an SSI rate of 8.6% per incision (2). Given the observational nature of the study and limited electronic follow up, SSI rates are likely to have been largely underestimated in this cohort.

2.3 Pillar-specific rationale

2.3.1 Justification for pillar-specific participant population

Vascular surgical access to the femoral vessels is one of the most common approaches performed daily by vascular surgeons worldwide. As previous observational studies and RCTs have demonstrated, the event rate for SSI is unacceptably high. It is estimated from national registry data that 7,000 groin incisions are performed in the UK each year (3). The quality of evidence to support individual interventions designed to reduce SSI in this population is poor. Patients with vascular disease requiring femoral artery access are a diverse population, with a mix of all ages, backgrounds and comorbidities.

2.3.2 Justification for choice of interventions

Intervention1: Epilation to remove hair prior to surgery

A Cochrane review suggests that patients who underwent shaving with a razor on the day of surgery were more likely to develop SSI than those who had used depilatory cream (relative risk 2.28, 95% confidence interval: 1.12 to 4.65)(4). However, most included studies were more than 20 years old and were at significant risk of bias. There are no comparisons with depilation using waxing or mechanical methods with clipping on the day of surgery. In vivo experiments demonstrate significant acceleration of healing during the anagen phase of hair follicle cycle stimulated by waxing/epilation(5, 6), which in theory could reduce the risk of SSI. A small feasibility study has demonstrated that epilation and waxing is safe and acceptable to patients once they are anaesthetised (7) .

A 2024 systematic review did not find any eligible studies to analyse that investigated the use of either of these adjuncts or their impact on SSI (8). There are no ongoing trials in vascular groin wounds investigating this area.

Intervention 2: Instrument change and Glove change prior to wound closure

This intervention has been conclusively shown to be effective in abdominal surgery in seven low-income and middle-income countries (absolute risk reduction: 0·87, 95% confidence interval 0·79-0·95; p=0·0032) (9). It is possible that instrument and glove change prior to wound closure will confer a similar benefit in vascular groin surgery, but it is not currently standard practice in the UK.

Intervention 3: Closed incision negative pressure wound therapy

A systematic review and meta-analysis identified that ciNPWT reduced groin wound SSI when compared to standard dressings (odds ratio: 0.34, 95% confidence interval 0.23 – 0.51; p<.001) (1). However, the studies in this review were all small, using variable and non-validated diagnostic criteria for SSI with a range of follow-up methods and durations. None assessed cost effectiveness, which given the disparity in price between ciNPWT and standard absorbent dressings warrants further robust exploration.

3. PILLAR SPECIFIC PILOT AIMS AND OBJECTIVES

3.1 Internal pilot objectives

The trial includes a 3-month internal pilot phase at Platform, Pillar and Intervention level.

The pilot phase of the vascular groin pillar will begin when the first patient is recruited to the pillar. The pilot phase will inform decisions on the continuation of the trial.

The aims of the internal pilot at Pillar level are to assess:

- Number of sites opened
- Number of patients recruited
- Engagement with the Centralised Digital Wound Hub (CDWH)
- Participant-level data at the Birmingham Clinical Trials Unit (BCTU)

At the end of the internal pilot phase, the Executive Trial Management Group (ETMG) and Trial Steering Committee (TSC) will review the pilot data against a set of pre-specified Red-Amber-Green (RAG) criteria:

Table 1: PILLAR Level Internal Pilot Progression Criteria

Progression Criteria	Number of sites opened	Participant recruitment	Engagement with CDWH*	Participant-level data to BCTU**
GREEN (GO)	≥ 8 sites	≥ 40 participants	≥ 95%	≥ 95%

AMBER (modify)	4 -7 sites	11 – 39 participants	≥ 90 - < 95%	≥ 90 - < 95%
RED (STOP)	≤ 3 sites	≤ 10 participants	< 90%	< 90%

* Percentage of participants submitting at least one response to CDWH

**Percentage of participants submitting baseline data to BCTU

Table 2: INTERVENTION-LEVEL Internal Pilot Progression Criteria

Progression Criteria	Compliance with randomised allocation by surgeon	Relative clinician acceptance of each intervention within the pillar[+]
GREEN (GO)	≥ 95%	≥ 80%
AMBER (modify)	≥ 85 - < 95%	≥ 60 - < 80%
RED (STOP)	< 85%	< 60%

[+] measured as willingness to accept it divided by its availability, considering site provision and participant eligibility prior to randomisation.

Intervention-level progression criteria relate to all interventions.

At the end of the first 3-month pilot, a second 3-month internal pilot can be triggered if deemed necessary by the Trial Steering Committee.

4. TRIAL DESIGN AND SETTING

4.1 Trial design

The VASCULAR GROIN pillar will be conducted as part of the ROSSINI-Platform trial (See Master Protocol). ROSSINI-Platform is a Basket Factorial Multi Arm Multi Stage (MAMS) platform trial with multiple phase III factorial MAMS RCTs running in parallel. The VASCULAR GROIN Pillar represents one of the phase III factorial MAMS RCTs.

The sample size for the VASCULAR GROIN pillar is 3,648 participants.

4.2 Trial setting

The VASCULAR GROIN Pillar will open in approximately 40 National Health Service (NHS) trusts in the UK. There are approximately 70 UK vascular centres. Since reconfiguration over a decade ago, vascular services are run in a 'hub and spoke' framework. Most arterial surgery is performed at vascular 'hubs', therefore these will be the main sites delivering the trial. Hubs are often located at large tertiary hospitals who offer a range of services and will likely be able to support multiple pillars within the platform.

5. PILLAR-SPECIFIC ELIGIBILITY

5.1 Inclusion criteria

- Patients aged 18 years or older
- Patients undergoing an emergency or elective groin incision(s) for arterial intervention including endarterectomy, embolectomy, thrombectomy, bypass, repair of (non-infected) traumatic injury (i.e. iatrogenic pseudoaneurysm) or exposure for an endovascular procedure within anatomical boundaries of the femoral triangle. This can include incisions that extend onto the abdomen or down the leg.
- Able to provide informed consent with the use of appropriate translation facilities if appropriate.

5.2 Exclusion criteria

- Groin surgery for infective complications, e.g. the groin is already infected (pseudoaneurysm, explanation of infected prosthetic material etc.)
- Groin exposure for venous access only without arterial exposure or intervention
- Groin exposure performed for cardiac procedures, e.g. Transcatheter Aortic Valve Implantation (TAVI); access for cardiac bypass
- For intervention 1: **Epilation**
    - Frail/fragile skin that is liable to tearing
    - Severe infection of intertrigo
    - Known allergy to waxing strips (epliators can be used if available in this circumstance)
- For intervention 3: **Closed incision negative pressure wound therapy (ciNPWT)**
    - Known allergy to material within the adhesive dressing used to deliver ciNPWT
    - Frail/fragile skin that is liable to tearing
- Patients who have undergone a groin incision in the previous 90 days

5.3 Co-enrolment

Patients who have been recruited to another RCT examining an intervention that does not share a common biological pathway with impact on the primary outcome measure, are permitted to be included within this pillar.

Sites should contact the ROSSINI-Platform Trials Office to discuss co-enrolment prior to patient recruitment.

6. PILLAR SPECIFIC CONSENT CONSIDERATIONS

Most patients undergoing surgery within the vascular groin pillar will be able to provide fully informed consent for entry into the ROSSINI-Platform trial.

The process for informed consent is detailed within the Master Protocol, and the options for provision of informed consent are described and must be followed for this pillar.

It is anticipated that most patients will provide face to face consent either on paper or electronically, however, any method of consent as detailed in the Master Protocol is acceptable.

7. RANDOMISATION and BLINDING

7.1 Randomisation method

There are three interventions being tested in this pillar. Participants will be randomised in a 1:1 ratio separately for each intervention.

Intervention 1 randomisation:

- Epilation of hair immediately prior to skin preparation (Intervention)
- Clipping of hair immediately prior to skin preparation (Control)

Intervention 2 randomisation:

- Change of surgical instruments and gloves prior to wound closure (Intervention)
- No change of surgical instruments and gloves prior to wound closure (Control)

Intervention 3 randomisation:

- Application of closed incisional topical negative pressure as a primary dressing (Intervention)
- Any dressing (not ciNPWT) considered standard of practice as a primary dressing (Control)

A minimisation algorithm will be used within the randomisation system to ensure balance in the intervention allocations over the following variables:

- Centre
- Synchronous bilateral groin incisions (unilateral OR bilateral)
- Diabetes (Yes (on medical therapy not including insulin) OR Yes (on insulin) OR, Yes (diet controlled) OR No)
- Smoking (Current smoker or nicotine use (including vaping/use of nicotine with cannabis) OR previous smoker OR never smoked)
- BMI (<30kg/m^2 OR ≥30kg/m2)
- Concurrent open wound and/or tissue loss on the ipsilateral lower limb below the groin (Yes OR No).

To avoid the possibility of the intervention allocation becoming predictable, a random element will be included in the algorithm. Full details of the randomisation specification will be stored in a confidential document at BCTU.

7.2 Blinding – Additional pillar-specific measures

Measures will be taken to ensure blinding to the randomised allocation as described in the Master Protocol (Section 7.5). No additional measures will be taken within the Vascular Groin Pillar.

Due to the nature of the study and proposed interventions, the blinding of participants or operators will not be possible.

8. PILLAR SPECIFIC TRIAL INTERVENTIONS

As a pragmatic RCT, ROSSINI-Platform does not mandate a specific bundle of care for the prevention of SSI as part of usual care in each trial centre, as this would limit wider generalisability of the findings.

Instead, it is stipulated that all trial sites should adhere to a minimum set of policies as per the National Institute for Health and Care Excellence (NICE) guidance CG74 (24) on the prevention of SSI. This includes:

- The monitoring and maintenance of normothermia
- Use of a standard three-stage World Health Organization (WHO) Surgical Safety Checklist.

8.1 Standard care

All patients undergoing a vascular operation to access the femoral artery will have their skin prepared using some form of antiseptic skin preparation, based on current evidence this is likely to be 2% alcoholic chlorhexidine.

The method of incision (transverse/longitudinal), wound closure (continuous vs. interrupted) and type of suture material (absorbable, non-absorbable, clips etc) will be left to the discretion of the operating clinician based on what they consider to be standard practice; however, this information will be recorded.

8.2 Trial interventions

Intervention 1: Epilation

Waxing or epilation (surgeon choice/availability) should 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. Any form of waxing strip or epilation device (not hair removal/depilation cream) can be used. The use of waxing or epilation should not be used in patients with significant intertrigo or very frail, fragile skin which could be prone to tearing (see exclusion criteria).

Comparator 1: Skin Clipping

Skin clipping of hair on the day of surgery, is deemed to be current standard of practice based on best available evidence (8). This can be performed using any currently available device by appropriately trained personnel. Skin clipping should take place perioperatively, usually once the patient has been anaesthetised and prior to skin preparation.

Intervention 2: Change of instruments and gloves prior to closure

For delivery of this intervention, we have opted to use a similar model to the routine sterile glove and instrument change at the time of abdominal wound closure to prevent surgical site infection as used in the ChEETAh cluster randomised trial (9). The recommendations below are adapted from this study.

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). This should be implemented in each hospital according to local resources and infrastructure. For example, instruments can be separated from the main instruments at the start of the operation by the scrub

nurse (eg, wrapped on a clean swab) or an entirely new instrument(s) pack opened. Drains or nerve catheters should be inserted prior to glove/instrument change.

Comparator 2: No change of instruments and gloves prior to closure

It is assumed that glove and instrument changes prior to wound closure is not the current standard practice in most vascular units. On occasion, changing gloves or instruments will occur at other points during the operation according to surgeon preference or routine practice and this can be continued as appropriate

Intervention 3: Closed incision topical negative pressure wound therapy

Following closure of the skin, using what each site considers standard of practice, any ciNPWT device should be applied according to manufacturer's guidance. Any device used in routine practice that is currently on the market can be used. 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. The device should be left on for 7 days, in line with the manufacturer guidance. The device should only be removed if there is a clinical need to do so in the best interest of the particpant. Device pressure should be set at the manufacturer's recommended guidance. Training materials for the application of ciNPWT can be provided if required for certain devices.

This intervention aims to evaluate ciNPWT as a therapy concept rather than evaluate any individual trademarked device. Our industry partner will provide ciNPWT devices to sites throughout the duration of the trial. Other ciNPWT devices are permitted for patients randomised to this intervention. Sites may have a pre-existing supplier of ciNPWT devices, it is anticipated that sites will utilise the devices supplied by our industry partner but can rely on any existing stock they may hold in any scenario where stock from the trial supplier are unavailable or based on the operating surgeon's preference.

Comparator 3: Standard dressing

Any dressing, other than ciNPWT can be used to cover the surgical wound, this includes active and non-active dressings, skin glue or any other suitable, market approved intervention that is routinely used at sites.

8.3 Contraindications

Specific contraindications to each included intervention are:

Intervention 1: Epilation

- Frail/fragile skin that is liable to tearing
- Severe infection or intertrigo
- Allergy to waxing strips (epilators can be used if available in this circumstance)

Intervention 2: Change of instruments and gloves prior to closure

None

Intervention 3: Closed incision negative pressure wound therapy (ciNPWT)

- Active bleeding or high risk of further bleeding
- Frail/fragile skin liable to tearing
- Allergy to dressings or adjuncts used to gain an adequate seal

8.3.1 Concomitant medication(s)/intervention(s)

Not applicable.

8.3.2 Prohibited medication(s)/intervention(s)

Not applicable as all medications used are topical and not considered to interact with systemic medications.

8.4 Intervention modification or discontinuation

Only applicable to intervention 3: CiNPWT

The following should be considered as reasons for discontinuation of ciNPWT:

- Patient intolerance or significant pain not controlled by simple analgesia
- Active bleeding
- New allergy to sealant adjuncts or materials
- Confirmed SSI (primary endpoint)

It is anticipated that for some patients allocated to the ciNPWT intervention, there may be periods during the intended therapy duration where an adequate seal is lost. Re-application of the ciNPWT dressing/device within the intended therapy period is permitted and does not constitute 'intervention modification'. Data pertaining to dressing/device reapplication will be recorded. If an adequate seal cannot be achieved during the intended therapy period, discontinuation of the intervention is permitted and will be recorded.

8.5 Cessation of treatment/ Continuation of intervention after the trial

The chosen method of hair removal is only performed once during the perioperative period and is therefore not continued.

The changing of instruments and gloves prior to closure occurs intraoperatively as a one-time event.

The use of ciNPWT should be continued as long as clinically appropriate and safe. Participant may return home with a device still in place on discharge from hospital. The length of device usage will be recorded for each participant but should be according to manufacturer's instructions as set out in Section 8.2.

8.6 Intervention supply and storage

8.6.1 Intervention supplies

The interventions used within the ROSSINI-Platform trial are either supplied free of charge by the manufacturer of the intervention or they are obtained from standard hospital stock.

For those interventions supplied for free directly form the manufacturer an initial supply of the interventions will be delivered to each site prior to site opening. The process for appropriate resupply and delivery arrangements will be explained during the Site Initiation Visit.

The provision of interventions for the Groin Pillar in the ROSSINI-Platform Trial are detailed below:

Intervention 1: Epilation

- TBC

Intervention 2: Change of instruments and gloves prior to closure

- No supplier required / not applicable – Standard hospital stock used

Intervention 3: Closed incision negative pressure wound therapy (ciNPWT)

- Industry partner
- Sites are permitted to use standard hospital stock

8.6.2 Packaging and labelling

There are no special packaging or labelling requirements for the interventions being used in the ROSSINI-Platform Vascular Groin Pillar.

Appropriate arrangements must be made to ensure availability of the Intervention(s) when needed, while also ensuring that Intervention(s) supplied for the trial are not used for non-trial indications. It is recommended that the trial interventions (or box in which they are held) be marked with a label "For ROSSINI-Platform Trial Use Only". The labels will be provided in the Investigator Site File (ISF) and are available from the ROSSINI-Platform Trial Office should sites require additional supplies.

8.6.3 Intervention storage

All interventions will be stored in a secure, clean, dry place free from damp at room temperature and within the supplied sterile packaging. No specific special requirements are required above the standard storage conditions of theatre products and refrigeration will not be necessary. Any excess intervention material will be disposed of in the hospital's standard clinical waste bins as per local hospital protocol. Interventions must only be used for patients within the trial, randomised to the arm in question. Any centres using those interventions supplied for free by the manufacturer outside of the trial setting may be cautioned, asked to withdraw from the trial or be asked for reimbursement.

8.6.4 Storage deviations

Not applicable. There are no special storage requirements for the interventions being provided free of charge via the ROSSINI-Platform trial office, and therefore we do not expect any storage deviation to occur

For any trial interventions that are from Hospital Standard stock, sites should follow local Policies and Standard Operating Procedures (SOPs).

8.6.5 Intervention recalls

In the event that trial intervention(s) provided via the ROSSINI-Platform Trial Office directly to participating sites, is recalled by the manufacturer, the ROSSINI-Platform Trial Office will promptly notify all participating sites and hospitals of the recall. The notification will include details of the recall, including the reason, the specific intervention batches affected (if these details have been provided by the manufacturer) and any immediate actions required (i.e. cease the use of the recalled intervention immediately, quarantine any remaining stock of the recalled intervention to prevent further use.

For any interventions not supplied via the ROSSINI-Platform Trial Office i.e. where the intervention is taken from standard hospital stock, sites should follow usual Trust procedures / recall SOPs for any intervention recalls.

8.7 Accountability

Each individual recruiting site shall be responsible for ensuring adequate stock of hair removal devices and consumables, as well as ciNPWT devices and adjuncts required to adequately randomise participants to all arms in the pillar. Each site must ensure that stock levels are adequate prior to randomisation to avoid protocol deviation.

9. PILLAR SPECIFIC ADVERSE EVENT REPORTING

Within the ROSSINI-Platform trial there are adverse events which are either:

1. Common to all pillars within the platform
2. Pillar-specific

The Master Protocol describes the process for adverse event reporting within the ROSSINI-Platform. This includes a description of:

- The reporting period for ALL safety events within the ROSSINI-Platform
- The process for reporting of ALL safety events within the ROSSINI-Platform
- Serious Adverse Events (SAEs) common to all pillars requiring expedited reporting within the ROSSINI-Platform
- SAEs common to all pillars requiring non-expedited reporting within the ROSSINI-Platform

Please refer to the Master Protocol for the process for safety reporting which must be followed.

9.1 Pillar-Specific Serious Adverse Events requiring non-expedited reporting to the Trial Office

Within this pillar, the expected intervention-specific adverse events are:

- Skin tearing or microtrauma and bruising from the use of waxing strips
- Intolerance or pain whilst the ciNPWT device is in use
- Blistering of skin or tearing of the skin due to the adhesive dressings used to achieve a seal for ciNPWT

These events require non-expedited reporting should be reported on the In-Theatre electronic Case Report Form (eCRF) or the Day of Discharge eCRF.

Events subject to non-expedited reporting and should be reported according to the process detailed in Section 11.5.2 of the Master Protocol.

10. REFERENCE LIST

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11. APPENDIX