Wound closure following hip arthroplasty

Submission date 25/01/2010	Recruitment status No longer recruiting	[X] Prospectively registered [] Protocol
Registration date 05/02/2010	Overall study status Completed	Statistical analysis planResults
Last Edited 13/03/2017	Condition category Surgery	Individual participant dataRecord updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Roland Ingram

Contact details

Glasgow Royal Infirmary Orthopaedics Department GateHouse Building Castle Street Glasgow United Kingdom G4 0SF

Roland.Ingram@ggc.scot.nhs.uk

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Wound closure following hip arthroplasty: a multicentre randomised controlled trial

Study objectives

Closing wounds, after total hip replacement, with DERMABOND® (skin glue) in addition to sutures will significantly decrease wound leakage and consequently surgical site infection rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West of Scotland Research Ethics Committee - pending approval as of 25/01/2010

Study design

Multicentre three-armed randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative wound leakage and surgical site infection

Interventions

All subjects in each of three randomised groups will have total hip arthroplasty wounds closed in layers with absorbable sutures. Subcuticular skin closure will be performed using monofilament suture (3/0 Biosyn) to oppose the wound edges. Each group will differ in the method of wound dressing.

Group 1:

A standard absorbent dressing will be applied to the wound.

Group 2:

DERMABOND® tissue adhesive will be applied to the dry wound in multiple thin layers. The width of the application will be approximately 5 mm either side of the incision. DERMABOND® will only be applied topically and never between wound edges. A standard absorbent dressing will be applied to the wound.

Group 3:

DERMABOND® tissue adhesive will be applied to the dry wound in multiple thin layers as for Group 2. A standard large Tegaderm™ dressing will then be applied to the wound.

The wound will be dressed for several weeks post-operatively but this will vary from patient to patient. Follow-up will be 3 months.

Intervention Type

Other

Primary outcome(s)

Wound leakage at 3 days post-operative

Key secondary outcome(s))

- 1. Wound complications including infection, assessed daily until patient is discharged and followed up at 3 months, and discharge, assessed daily until patient is discharged from hospital. Any discharge beyond day 4 will be classified as prolonged
- 2. Time to discharge
- 3. Cosmetic appearance, measured using a modified Hollander Scale to assess cosmesis at 3 months post-operatively
- 4. Pain, measured using a visual analogue scale to assess pain daily until discharge and at 3 months

Completion date

01/04/2011

Eligibility

Key inclusion criteria

- 1. Anyone requiring elective Total Hip Replacement at Glasgow Royal Infirmary or Royal Alexandra Hospital (Paisley)
- 2. Able to give informed consent
- 3. Aged over 18 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Known glue allergy
- 2. Coagulation disorder
- 3. Unable to give informed consent

Date of first enrolment

05/04/2010

Date of final enrolment

01/04/2011

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre Glasgow Royal Infirmary Glasgow United Kingdom G4 0SF

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type

Charity

Funder Name

Glasgow Royal Infirmary (UK) - Orthopaedic Endowment Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No