

Wound closure following hip arthroplasty

Submission date 25/01/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/03/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Wound leakage at 3 days post-operative

Secondary outcome measures

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

Overall study start date

05/04/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

219 in three groups

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**

Scotland

United Kingdom

Study participating centre

Glasgow Royal Infirmary

Glasgow

United Kingdom

G4 0SF

Sponsor information**Organisation**

NHS Greater Glasgow and Clyde (UK)

Sponsor details

R&D Management Office

Western Infirmary

38 Church Street

Glasgow

United Kingdom

G11 6NT

Sponsor type

Government

Website

<http://www.nhs.uk/content/>

ROR

<https://ror.org/05kdz4d87>

Funder(s)**Funder type**

Charity

Funder Name

Glasgow Royal Infirmary (UK) - Orthopaedic Endowment Fund

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration