ISRCTN70685656 https://doi.org/10.1186/ISRCTN70685656

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 plan [_] Results
Last Edited 13/03/2017	**Condition category** Surgery	[_] Individual participant data [_] 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.nhsggc.org.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