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Fibrin sealant to reduce blood loss after hip replacement

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/04/2015	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0234117607

Study information

Scientific Title
Fibrin sealant to reduce blood loss after hip replacement

Study objectives
Does fibrin sealant reduce blood loss after primary and revision hip replacement?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Hip replacement

Interventions
Two groups: Revision total hip replacement and Primary total hip replacement.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Quantitative estimate of per-operative blood loss, measurement of post-operative blood loss volume via drains, post-operative haemaglobin level, number of patients requiring blood transfusion.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2002

Completion date
31/07/2003

Eligibility

Key inclusion criteria
Primary hip replacement: 60 patients not on anticoagulant medications, without blood autoantibodies and with pre-operation Hb level >12.5 will be randomised into treatment and control groups.
Revision hip replacement: 30 consecutive patients in treatment group not randomized. Control group will be historical, with information regarding blood loss gained from a retrospective review of notes.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
90

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2002

Date of final enrolment
31/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust (UK)

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