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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration