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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Contact details

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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