# 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

Mr DKA Smart

### Contact details

Department of Orthopaedics (AOC) North Bristol NHS Trust Southmead Hospital Westbury-on-Trym Bristol United Kingdom BS10 5NB

# 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