A randomised controlled trial of the use of topical application of tranexamic acid in primary cemented total hip replacement

Submission date	Recruitment status	Prospectively registered		
29/09/2006	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
29/09/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
22/09/2014	Musculoskeletal Diseases			

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 N0155164510

Study information

Scientific Title

Study objectives

Can we reduce blood loss associated with total hip replacement by using topical tranexamic acid?

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West MREC Greater Manchester Strategic Health Authority, ref 05/MRE08/10, favourable ethical opinion on 11/04/2005, extended 02/02/2006

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: total hip replacement

Interventions

Randomised controlled trial

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Tranexamic acid

Primary outcome(s)

Reduction in blood loss

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients having unilateral primary cemented total hip replacement

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. Allergic to tranexamic acid
- 2. Pregnancy
- 3. History of DVT/pulmonary embolus
- 4. Patients involved in other trials
- 5. Known bleeding problems
- 6. Concurrent treatment with warfarin
- 7. Low dose molecular weight heparin or conventional heparin
- 8. Paget's disease or revision total hip replacement

Date of first enrolment

01/06/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Dept of Orthopaedics

Bury United Kingdom BL9 7TD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Pennine Acute Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created Date adde	d Peer reviewed	? Patient-facing?
Results article	results	06/11/2013	Yes	No
Participant information shee	Participant information sheet	11/11/2025 11/11/202	.5 No	Yes