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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

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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 added	Peer reviewed?	Patient-facing?
Results article	results	06/11/2013		Yes	No