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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Reduction in blood loss

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Patients having unilateral primary cemented total hip replacement

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
124

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
England

United Kingdom

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0) 20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Pennine Acute Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/11/2013		Yes	No