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Effects of tranexamic acid in total knee arthroplasty - pilot study

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/04/2011	Surgery	

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
N0162147151

Study information

Scientific Title

Study objectives
To establish whether tranexamic acid can reduce bleeding after knee replacement surgery without increasing the risk of deep venous thrombosis.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Total knee arthroplasty

Interventions
Prospective, randomised controlled trial of 15 mg/ kg tranexamic acid v equivalent volume of normal saline given iv prior to tourniquet release during TKA

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
tranexamic acid

Primary outcome measure
1. Blood loss in the first 48 hours post op
2. Transfusion requirements
3. Screen-detected DVT

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2000

Completion date
31/05/2004

Eligibility

Key inclusion criteria
15 patients, 15 control patients of any age who are planned to have total knee arthroplasty

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2000

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept Orthopaedics
Northampton
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Northampton General Hospital NHS Trust (UK), R&D NHS support funding

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	01/03/2006		Yes	No