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Effects of tranexamic acid in total knee arthroplasty - pilot study

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

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
1. Blood loss in the first 48 hours post op
2. Transfusion requirements
3. Screen-detected DVT

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Dept Orthopaedics
Northampton
United Kingdom
NN1 5BD

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name

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

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	01/03/2006		Yes	No