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

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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

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