# Effects of tranexamic acid in total knee arthroplasty - pilot study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

Mr Christopher Little

#### Contact details

Dept Orthopaedics Northampton General Hospital NHS Trust Northampton United Kingdom NN1 5BD

# 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 NN1 5BD

# Sponsor information

#### Organisation

Department of Health

#### Sponsor details

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

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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults01/03/2006YesNo