ISRCTN09327299 https://doi.org/10.1186/ISRCTN09327299

A prospective randomised trial of the use of tourniquet in total knee replacements

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/11/2019	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr David Johnson

Contact details
Orthopaedics
Aspen House
Stepping Hill Hospital
Poplar Grove
Stockport
United Kingdom
SK2 7JE
-
David.Johnson@stockport.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0244192302

Study information

Scientific Title
A prospective randomised trial of the use of tourniquet in total knee replacements

Study objectives
To investigate the short-term outcomes of inflating the tourniquet only during the cementation process.

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)
Hospital

Study type(s)
Treatment

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

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

Interventions
Intervention: Tourniquet only inflated during cementation of the replacement.
Control: Tourniquet inflated throughout procedure as in routine practice.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Blood loss and change in haemoglobin level day 2 post-operatively

Secondary outcome measures
1. Range of movement six weeks post-op
2. Post-operative wound problems
3. Operative time
4. Blood transfusion
5. Complication rate

Overall study start date
01/11/2006

Completion date
01/11/2007

Eligibility

Key inclusion criteria
All patients undergoing total knee replacement at Stepping Hill Hospital under two named consultant surgeons

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
252

Key exclusion criteria
1. History of peripheral vascular disease with absent popliteal or distal pulses
2. Calcification of artery on x-ray of knee
3. Previous vascular surgery on side of operation

Date of first enrolment
01/11/2006

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stepping Hill Hospital
Stockport
United Kingdom
SK2 7JE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 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
Stockport NHS Foundation Trust

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