ISRCTN94713892 https://doi.org/10.1186/ISRCTN94713892

Does intramedullary plugging reduce blood transfusion requirements in total knee replacement?

Submission date	Recruitment status	[ ] Prospectively registered
18/12/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/02/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/05/2017	Surgery	[ ] Record updated in last year

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
Version 1, dated 24.08.09

Study information

Scientific Title
Does intramedullary plugging reduce blood transfusion requirements in total knee replacement? A randomised controlled clinical trial

Study objectives
To assess if intramedullary plugging, when used together with an autologous retransfusion drain, reduces blood loss to make significant differences in allogenic blood requirements in patients undergoing total knee replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee (REC), 20/11/2009, ref: 09/H0505/117

Study design
Randomised controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Trauma and Orthopaedics - total knee replacements

Interventions
Patients who have total knee arthroplasty will be randomised into two groups. One group will have intramedullary plugging with retransfusion drains and one group will have retransfusion drains only.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Allogenic blood transfusion requirements

Secondary outcome measures
Post-operative blood loss assessed by:
1. Haemoglobin levels in first 3 days of the post-operative period
2. Total amount of blood collected in drain in the first 24 hours after surgery

Overall study start date
24/12/2009

Completion date
30/01/2011

Eligibility

Key inclusion criteria
1. Male and female patients
2. Aged 50-90 years
3. Undergoing primary total knee replacement surgery

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
100

Key exclusion criteria
Patients undergoing unicompartmental knee replacements and revision knee replacements

Date of first enrolment
24/12/2009

Date of final enrolment
30/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Berkshire NHS Foundation Trust
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
Royal Berkshire NHS Foundation Trust (UK)

Sponsor details
c/o Leslie Frederick
Research and Development Office
Royal Berkshire NHS Foundation Trust
London Road
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England
United Kingdom
RG1 5AN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/034nvrd87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Berkshire NHS Foundation Trust (UK) - Trauma and Orthopaedic Department

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