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

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

Primary study design
Interventional

Study design
Randomised controlled parallel-group trial

Study type(s)
Treatment

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(s)
Allogenic blood transfusion requirements

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Royal Berkshire NHS Foundation Trust (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration