

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

Submission date 18/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/02/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/05/2017	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Study design

Randomised controlled parallel-group trial

Primary study design

Interventional

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/034nvr87>

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