

Are autotransfusion drains effective for total knee arthroplasty? A randomised controlled trial

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/05/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data

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
N0114126741

Study information

Scientific Title

Study objectives

Do autotransfusion drains obviate the need for formal blood transfusion with cross-matched blood after total knee arthroplasty?

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

Study type(s)

Other

Health condition(s) or problem(s) studied

Surgery: Knee arthroplasty

Interventions

At the pre-admission clinic the patients will be randomly allocated into one of two groups (50 patients in each group) after discussing the project with them, providing them with a patients information leaflet and consenting them. One group will receive all their post operatively drained wound blood back as an autotransfusion using the "Bellovac" autotransfusion drain system. The other group will have their wound blood discarded and be transfused according to preset criteria. The autotransfused patients may need additional transfusion with cross-matched blood if they fail to meet the preset criteria.

Transfusion criteria:

1. A loss of >1000 ml of blood in the collection drain;
2. A clinical need for transfusion (Tachycardia, hypotensive, ischaemic electrocardiogram [ECG] changes)
3. A haemoglobin blood level of <8.5 g/dl.

The data will be collated to determine by simple non-parametric statistical analysis whether autotransfusion drains are useful in obviating the need for conventional transfusion with cross-matched donated blood. A publication in the Journal of Bone and Joint Surgery is anticipated.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Post operative Haemoglobin levels (checked at 12, 24 and 72 hours)

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2003

Eligibility

Key inclusion criteria

100 patients will be selected for this study. All patients will need total knee replacements.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Patients with bleeding disorders, Jehovah's witnesses and those not wishing to enter the study will be excluded.

Date of first enrolment

01/07/2003

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Colchester General Hospital

Colchester

United Kingdom

CO4 5JL

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Colchester Hospital University NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2008		Yes	No