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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 16/05/2012	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

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

England

United Kingdom

Study participating centre
Colchester General Hospital
Colchester
United Kingdom
CO4 5JL

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Colchester Hospital University NHS Foundation Trust (UK)

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

Study outputs

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