

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/05/2012	<b>Condition category</b> 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?
<a href="#">Results article</a>	results	01/04/2008		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes