

# A prospective randomised controlled trial to determine the nature of the immunostimulants in autologous salvaged blood

<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> 01/05/2012	<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

### Contact name

Prof B A Bradley

### Contact details

Department of Transplantation Sciences  
North Bristol NHS Trust  
Southmead Hospital  
Westbury-on-Trym  
Bristol  
United Kingdom  
BS10 5NB  
+44 (0)117 959 5340

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0234135785

## Study information

### Scientific Title

### Study objectives

What component of autologous salvaged blood reverses the immunosuppression resulting from surgery and blood loss?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

No ethics information 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)

Screening

### 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: Autologous salvage transfusion

### Interventions

Randomised into three groups according to the type of postoperative autogous salvage transfusion.

### Intervention Type

Procedure/Surgery

### Phase

Not Specified

### Primary outcome measure

In vitro measures of immune status including changes in cytokine profiles and populations of certain lymphocyte subsets in whole blood.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/2004

**Completion date**

31/03/2005

## Eligibility

**Key inclusion criteria**

60 patients undergoing total knee arthroplasty at Avon Orthopaedic Centre randomised into three groups according to type of post-operative autologous salvage transfusion.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

60

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/04/2004

**Date of final enrolment**

31/03/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of Transplantation Sciences**  
Bristol  
United Kingdom  
BS10 5NB

## **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**

North Bristol NHS 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?
<a href="#">Results article</a>	results	27/03/2004		Yes	No