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

Submission date	Recruitment status No longer recruiting	Prospectively registered	
30/09/2004		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
30/09/2004	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
01/05/2012	Surgery		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof B A Bradley

#### Contact details

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# Additional identifiers

**Protocol serial number** 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

# Study type(s)

Screening

### 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(s)

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

#### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

# Healthy volunteers allowed

No

# Age group

Adult

#### Sex

**Not Specified** 

# 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

**United Kingdom** 

England

# Study participating centre Department of Transplantation Sciences

Bristol
United Kingdom

BS10 5NB

# Sponsor information

# Organisation

Department of Health

# Funder(s)

# Funder type

Hospital/treatment centre

# Funder Name

North Bristol NHS 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	27/03/2004	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	5 No	Yes