ISRCTN64731819 https://doi.org/10.1186/ISRCTN64731819

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

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 01/05/2012	**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

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