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Autologous Transfusion In Surgery: a randomised clinical trial

Submission date 23/01/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/01/2004	**Overall study status** Stopped	
Last Edited 21/01/2010	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Charles McCollum

Contact details
Academic Surgery Unit
2nd Floor ERC
University Hospital of South Manchester
Southmoor Road
Manchester
United Kingdom
M23 9LT
+44 (0)161 291 5853
cnmcc@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RHC18069

Study information

Scientific Title

Acronym
ATIS

Study objectives
Does autologous transfusion reduce the use of homologous stored blood?

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Peripheral arterial disease

Interventions
1. Autologous transfusion: acute normovolaemic haemodilution and intragerative cell salvage
2. Homologous transfusion: homologous blood if required

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Blood transfusion requirements, haematological and haemostatic parameter, post-operative infection, morbidity and hospital stay, economic analysis

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/1997

Completion date
01/10/1999

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
All patients undergoing elective surgery for either occlusive or aneurysmal arterial disease will be asked to give written informed consent:
1. Both men and women aged 30-85
2. Considered fit for aortic surgery without any of the exclusion criteria
3. Pre-operative haemoglobin >11 g/dl and platelet count >150 x 10^9/1
4. Adequate cardiac and pulmonary function clinically

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Any patient unfit for aortic surgery, unable for any reason to receive either autologous or standard transfusion therapy, or undergoing emergency surgery for suspected rupture of an aneurysm.

Date of first enrolment
01/10/1997

Date of final enrolment
01/10/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Surgery Unit
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (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