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A randomised trial using Zero-Balanced Ultrafiltration in Cardiopulmonary bypass

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/04/2018	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0123138588

Study information

Scientific Title
A randomised trial using Zero-Balanced Ultrafiltration in Cardiopulmonary bypass

Study objectives
To show whether a modified method of ultrafiltration, known as Zero-balance ultrafiltration (ZBUF) is effective in reducing free-radical production during cardiac surgery in adults. A reduction in free radical generation will help protect cell membranes

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 surgery

Interventions
Clinical Study|Human Physiology|Inpatient Admission|Multicentre Study: National|NHS Patients|Study of Non-Therapeutic Procedure

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
To establish the effects of Zero-balanced Ultrafiltration with patients in cardiopulmonary bypass

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/08/2003

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Less than 75 years of age
2. Left ventricular function less than 50%
3. Pre-operative haematocrit greater than 30%.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/08/2003

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

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
University Hospitals of Leicester 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