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Fat Filtration and Organ Injury following Cardiac Surgery

Submission date	Recruitment status	[_] Prospectively registered
24/08/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2017	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

Protocol serial number
REM09

Study information

Scientific Title

Quantification of lipid and leukocyte filtration and the effects on cerebral and renal injury markers and pulmonary function during cardiopulmonary bypass.

Study objectives
The hypothesis being tested is that the filtration of lipid emboli and activated leucocytes from the blood will result in lower levels of organ injury as seen by biochemical marker analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Oxford Research Ethics Committee C, 25/06/2009, ref: 10/H0606/30

Primary study design
Interventional

Study design
Single-centre blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiopulmonary bypass

Interventions
Use of the RemoweLL Oxygenator containing a lipid and leucocyte depleting filter against current standard oxygenator during cardiopulmonary bypass for patients undergoing coronary artery bypass grafting.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
1. Concentration of lipid microemboli measured using light microscopy and Oil Red O staining before and after cardiopulmonary bypass compared to control
2. Percentage of activated leucocytes using flow cytometry marker CD11b before and after cardiopulmonary bypass compared to control

Key secondary outcome(s)
Levels of biochemical markers of organ injury, specifically
1. Brain (neuron-specific enolase [NSE])
2. Kidneys (Cystatin C and standard laboratory tests) and
3. Pulmonary function as measured by calculation of the respiratory index
Comparison between before and after results with trial and standard oxygenator.

Completion date

06/09/2012

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study - any documented history of cognitive impairment will exclude the patient as this may have an effect on biochemical markers of cerebral injury
2. Male or female, aged 18 years or above
3. Patients undergoing elective Coronary Artery Bypass Graft (CABG) surgery
4. Angiographically proven coronary artery stenosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Age less than 18 or more than 90 years old
2. Emergency CABG surgery
3. Previous CABG surgery
4. Gross haemodynamic instability:
4.1. Hypertension (systolic blood pressure >160mmHg)
4.2. Hypotension (systolic blood pressure <90mmHg)
4.3. Bradycardia (heart rate <60 beats/min)
5. Diabetes
6. Obesity (BMI >30)
7. Pre-operative heparin regime
8. Abnormal preoperative white cell count (<4 or >10x109 cells/L)
9. Renal failure (serum creatinine >150µmol/L)

Date of first enrolment
06/09/2010

Date of final enrolment
06/09/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Eurosets s.r.l. (Italy)

ROR
https://ror.org/02pqj5664

Funder(s)

Funder type
Industry

Funder Name
Eurosets s.r.l. (Italy)

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?
Protocol article	results	02/02/2016		Yes	No