ISRCTN56462370 https://doi.org/10.1186/ISRCTN56462370

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

Contact name
Mr Richard Issitt

Contact details
Perfusion Department, Level 1 Theatres
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
-
richardissitt@btinternet.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
06/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 patients, 25 in each group

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
England

United Kingdom

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

Sponsor information

Organisation
Eurosets s.r.l. (Italy)

Sponsor details
Strada Statale 12
n°143
Medolla
Italy
41036

Sponsor type
Industry

ROR
https://ror.org/02pqj5664

Funder(s)

Funder type
Industry

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	results	02/02/2016		Yes	No