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The impact of continuous haemofiltration during cardiopulmonary bypass on cardiac surgery patients with impaired renal function

Submission date	Recruitment status	[X] Prospectively registered
07/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/11/2019	Urological and Genital Diseases	

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
704

Study information

Scientific Title

The impact of intra-operative haemofiltration during on-pump cardiac surgery on biomarkers of oxidative stress and healthcare outcomes of patients with impaired renal function: a pilot randomised trial

Acronym
HAEMOTRACKER-TRIAL

Study objectives
The application of haemofiltration during cardiopulmonary bypass (CPB) reduces time to tracheal extubation, length of mechanical ventilation and attenuates post-operative anaemia, thrombocytopenia, hypoalbuminemia, post-operative bleeding and post-operative pulmonary complications and this would be the basis for a reduction in intensive care unit (ICU) stay, peri-operative complications and overall length of hospital stay in patients with impaired kidney function undergoing cardiac operations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Liverpool Heart and Chest Hospital, Medical Reseach Ethics Committee (MREC), 31/12/2009, ref: 09/H1005/71

Study design
Pilot single-blind randomised controlled single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pre-operative renal impairment/coronary heart disease/coronary heart interventions

Interventions
Current information as of 26/03/10:
Eligible patients will be randomised to one of the following groups:
1. Control group: ON-pump high risk cardiac (coronary artery bypass graft (CABG) alone, valve surgery, CABG plus valve) surgery patients with GFR <50 ml/min without haemofiltration
2. Experimental group: ON-pump high risk cardiac (coronary artery bypass graft (CABG) alone, valve surgery, CABG plus valve) patients with GFR <50 ml/min undergoing haemofiltration

Study timetable:
Start of recruitment: April 2010 - Mar 2013
End of follow-up: Apr 2013
Analysis and reporting: May 2013 - Jul 2013
Final report: Sep 2013

Initial information at time of registration:
Patients that fulfil inclusion and exclusion criteria will be asked to give consent for the study and

will be randomised into the two study groups by a computer-generated programme:
1. ON-pump isolated CABG patients with GFR less than 60 ml/min without haemofiltration (control arm)
2. ON-pump isolated CABG patients with GFR less than 60 ml/min undergoing haemofiltration

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current information as of 26/03/10:
Length of ICU stay for non-dialysis patients with impaired kidney function (estimated glomerular filtration rate <50 ml/min)

Initial information at time of registration:
Incidents of ICU stay greater than 3 days for patients with eGFR less than 60 ml/min.

Key secondary outcome(s))
Current information as of 26/03/10:
1. Clinical Outcomes
1.1. Duration of Hospital stay
1.2. Myocardial infarction
1.3. The mean eGFR/creatinine clearance values at hospital discharge
2. Biomarkers Outcomes:
2.1. Plasma levels of protein nitration
2.2. 8-isoprostanes
2.3. Malondialdehyde levels
2.4. Plasma and erythrocyte reduced/oxidised glutathione (GSH/GSSG) ratio
2.5. Urinary N-acetyl-D-glucosamine (D-NAG) excretion
2.6. Highly sensitive C-reactive protein (hsCRP)
2.7. Tumour necrosis factor alpha (TNF-α)
Measured at baseline, during CPB, 24 hours and 48 hours after the operation.
3. Secondary Economic Outcomes:
Resource utilisation and key costs indicators associated with each of the two pilot arms estimated up until hospital discharge. Specifically:
3.1. ICU stay and hospital stay
3.2. Postoperative renal replacement therapy
3.3. Mechanical ventilation
3.4. Medications

Initial information at time of registration:
1. Clinical outcomes:
1.1. Overall length of hospital stay
1.2. Need for renal support post-operatively
1.3. Mechanical ventilation time
1.4. Length of tracheal intubation
1.5. Arrhythmias
1.6. The worst eGFR/creatinine clearance values during hospital stay
1.7. Myocardial infarction
2. Biomarker outcomes:
Markers of oxidative stress and the systemic inflammatory response.
3. Cost outcomes:

Resource utilisation and costs associated with the intra-operative haemofiltration, care at the ICU and ward and adverse events (e.g., bleeding complications, sepsis), requirement for post-operative haemofiltration will be measured. Since the number of operations performed in most cardiac centres depend on availability of ICU beds, the implications for the productivity of the ICU unit will be explored by simulating its activity and resource flows and outcomes, in terms of operations performed per unit time (e.g., a year).

Patients will be followed-up for all secondary outcome measures until the time of hospital discharge.

Completion date
01/09/2013

Eligibility

Key inclusion criteria
Current information as of 26/03/10:
1. Consenting men and women aged at least 18 years old
2. High-risk patients elective for on-pump valve replacement, coronary artery bypass graft surgery (CABG) or combined CABG and valve procedures
3. Patients with impaired renal function established preoperative by an estimated glomerular filtration rate (eGFR) <50 ml/min

Initial information at time of registration:
1. Male and female patients, at least 18 years old
2. Elective for on-pump coronary artery bypass graft surgery (CABG)
3. Patients with impaired renal function established by pre-operative estimated glomerular filtration rate (eGFR) less than 60 ml/min

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
199

Key exclusion criteria
Current information as of 26/03/10:
1. Patients scheduled to undergoing cardiac surgery with anticipated CPB time <60 minutes

2. Patients undergoing surgery on the great vessels (aortic surgery)
3. Patients with significant impaired liver function (serum bilirubin > 60 or INR >2 without anticoagulation)
4. Patients who are further down the line of renal failure (i.e. eGFR <15 ml/min)
5. Patients on-dialysis
6. Presence of malignancy
7. Pregnancy

Initial information at time of registration:
1. Undergoing valve replacement surgery
2. Patients with significant impaired liver function (serum bilirubin greater than 60 or international normalised ratio [INR] greater than 2 without anticoagulation)
3. Patients on-dialysis
4. Patients that are pregnant or have malignancy

Date of first enrolment
01/04/2010

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Heart and Chest Hospital
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Sponsor information

Organisation
Liverpool Heart and Chest Hospital NHS Trust (UK)

ROR
https://ror.org/01je02926

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - DH CSO Healthcare Scientist Research Fellowship

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	01/10/2015	04/11/2019	Yes	No
Other publications	post-hoc analysis of biomarker levels	01/10/2019	04/11/2019	Yes	No