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Outcomes of intraoperative haemofiltration for patients with impaired kidney function undergoing coronary artery bypass graft surgery

Submission date
26/03/2010

Recruitment status
No longer recruiting

Registration date
06/07/2010

Overall study status
Completed

Last Edited
07/06/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is estimated that up to 20 in 100 patients undergoing cardiac (heart) surgery have a pre-existing kidney impairment that is associated with an increased risk of death during or after the operation. Earlier studies have demonstrated that applying blood filtration (haemofiltration) within the first 48 hours after the operation halves the risk of death. The performance of the procedure two days after surgery may be too late to protect the patient's kidneys from further injury. The aim of this study is to investigate whether haemofiltration performed at the point when the patient is connected to the heart and lung bypass machine during surgery may be more beneficial.

Who can participate?
Patients aged 18 or over, undergoing on-pump coronary artery bypass graft surgery, and who have impaired kidney function.

What does the study involve?
Participants are randomly allocated into two groups. The control group undergo on-pump coronary artery bypass graft surgery without haemofiltration. The intervention group undergo on-pump coronary artery bypass graft surgery with haemofiltration. Participants are followed after the operation to determine their kidney function and length of ICU stay.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Liverpool Heart & Chest Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2010 to July 2011

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/53/33; 853

Study information

Scientific Title
The impact of continuous haemofiltration with high volume fluid exchange during cardiopulmonary bypass surgery on the recovery of patients with impaired renal function - a pilot study

Acronym
FOBS (Filtration on Bypass Surgery)

Study objectives
We hypothesise that intraoperative haemofiltration significantly reduces incidences of intensive care unit stay longer than 3 days for patient with preoperative impaired kidney undergoing coronary artery bypass graft surgery.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/085333
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0010/53002/PRO-08-53-33.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Liverpool Heart and Chest Hospital, Medical Research Ethics Committee (MREC), 09/06/2010

Study design
Pilot single-blind randomised controlled single-centre 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Preoperative renal impairment; coronary heart disease; cardiac artery bypass graft surgery

Interventions
Patients that fulfil inclusion and exclusion criteria will be fully informed about the study and asked to give consent for the study. They will be randomised into two study groups by a computer-generated programme:
1. Control group: Patients with estimated GFR <60 ml/min undergoing ON-pump coronary artery bypass graft surgery without intraoperative haemofiltration
2. Intervention group: Patients with estimated GFR <60 ml/min undergoing ON-pump coronary artery bypass graft surgery with intraoperative haemofiltration

Intervention Type
Procedure/Surgery

Primary outcome measure
Incidents of ICU stay >3 days for patients with renal impairment identified as an estimated glomerular filtration (eGFR) <60 ml/min

Secondary outcome measures

1. Clinical outcomes:
1.1. Composite of perioperative incidences:
1.1.1. Bleeding
1.1.2. Sepsis
1.1.3. Death
1.1.4. Arrhythmias
1.1.5. Stroke
1.1.6. Myocardial infarction
1.2. Need for postoperative continuous veno-venous haemofiltration (CVVH) in the ICU and wards - Indications for requirement of postoperative continuous veno-venous haemofiltration must adhere to our strict NHS Trust criteria and guidelines.
1.3. Mechanical ventilation time
1.4. Hospital stay
1.5. eGFR at 6 weeks follow-up
2. Economic outcomes: Resource utilisation and costs associated with each of the two pilot arms such as:
2.1. ICU stay and hospital stay
2.2. Mechanical ventilation
2.3. Medications
2.4. Tests and procedures undertaken until the end of the follow-up period

Overall study start date
01/07/2010

Completion date
30/07/2011

Eligibility

Key inclusion criteria
1. Consenting men and women must be at least 18 years old
2. High-risk patients elective for on-pump coronary artery bypass graft surgery (CABG)
3. Impaired renal function established preoperatively by an estimated glomerular filtration rate (eGFR) <60 ml/min measured within 4 weeks before surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients undergoing surgery on the great vessels (aortic surgery)
2. Patients with significantly impaired liver function (serum bilirubin> 60 or INR>2 without anticoagulation)
3. Patients who are further down the line of renal failure or on-dialysis
4. Patients with malignancy
5. Those that are pregnant

Date of first enrolment
01/07/2010

Date of final enrolment
30/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool Heart and Chest Hospital
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Sponsor information

Organisation
Liverpool Heart & Chest Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website

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ROR
https://ror.org/000849h34

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/10/2013		Yes	No