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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>			
26/03/2010		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
06/07/2010	Completed	[X] Results			
Last Edited	Condition category	Individual participant data			
07/06/2016	Urological and Genital Diseases				

#### 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 preexisting 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? Dr Bashir Matata bashir.matata@lhch.nhs.uk

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Bashir Matata

#### Contact details

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## Additional identifiers

#### Protocol serial number

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

## Study type(s)

Treatment

#### 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(s)

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

## Key secondary outcome(s))

- 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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

## Study participating centre Liverpool Heart and Chest Hospital Liverpool United Kingdom L14 3PE

## Sponsor information

#### Organisation

Liverpool Heart & Chest Hospital NHS Foundation Trust (UK)

#### **ROR**

https://ror.org/000849h34

## Funder(s)

#### Funder type

Government

#### **Funder Name**

Health Technology Assessment Programme

#### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

#### **Funding Body Type**

Government organisation

#### Funding Body Subtype

National government

#### Location

**United Kingdom** 

## **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes