ISRCTN47114813 https://doi.org/10.1186/ISRCTN47114813

# Does haemodynamic optimisation, as guided by Oesophageal Doppler Monitoring, produce a greater reduction in complications and length of stay, if used intra-operatively, post-operatively or both?

| | | |
|---|---|---|
| **Submission date**<br>28/09/2007 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>28/09/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>04/09/2015 | **Condition category**<br>Surgery | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Ms Annette Smith

**Contact details**
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N0051189167

# Study information

### Scientific Title
Does haemodynamic optimisation, as guided by Oesophageal Doppler Monitoring, produce a greater reduction in complications and length of stay, if used intra-operatively, post-operatively or both?

### Study objectives
1. Does haemodynamic optimisation, as guided by Oesophageal Doppler Monitoring (ODM), produce a greater reduction in complications and length of stay, if used intra-operatively, post-operatively or both?
2. Objective: To compare the use of ODM to guide fluid management and optimise haemodynamic status (maintaining blood/fluid volume within the bodies circulation and ensuring that the patients Blood Pressure and heart function is adequate to supply the other organs of the body), at different stages of the surgery:
2.1 During the operation
2.2 Immediately after the operation until the patient is weaned off the ventilator (breathing machine)
2.3 Combined during and immediately after the operation until weaned off the ventilator.
The 3 groups will be compared to see which gives the greatest reduction in the length of hospital stay, from the operation date to the day of discharge. ODM uses a silicone probe inserted into the oesophagus to monitor heart function. It does this by measuring the velocity of the blood flow in the descending aorta (the main artery from the heart supplying the body). The information obtained can be used to guide fluid management in critically ill patients or during major surgery, in combination to the routine measures used of Blood Pressure (BP) pulse, urine output and blood loss.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised pilot study

### 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
Surgery: Coronary artery bypass grafting (CABG)

## Interventions
This will be a pilot study that will investigate/compare fluid optimisation of adult patients at different stages of their surgical experience.

There will be three groups in the study:
1. Intra-operative fluid optimisation as guided by ODM.
2. Post-operative fluid optimisation as guided by ODM (until extubation/weaned off the ventilator).
3. Combined Intra and Post-operative fluid optimisation as guided by ODM (until extubation).

An internet and journal database search of literature on the used of ODM as a guide to fluid optimisation found that it reduces hospital stay and post-operative complications. Most of the studies used ODM during the operation. One (involving patients having heart surgery) used ODM immediately after the operation. Therefore it would appear valid to investigate which provides the best outcome in terms of reduced hospital stay or whether a greater benefit is obtained by a combination of the two.
The primary objective is to compare the three groups to see which one produces the best result in reducing length of hospital stay. The secondary objective is to compare post-operative complications, specifically that of post-operative nausea, arrhythmias and renal complications. Nausea or vomiting can be measured by the anti-emetics given on the drug chart or vomiting on the fluid chart. Arrhythmias will be measured by any arrhythmia that caused haemodynamic instability and to investigate renal complications the increase in the blood creatinine and urea from routine blood results will be analysed.

The Doppler probes will be inserted in theatre during surgery by a consultant anaesthetist. This will mean that the nursing staff will not be aware which group the participant is in. The participants in group one will receive standard post-operative care when they arrive in the Intensive Care Unit (ICU). All participants will receive standard post-operative care once they have been extubated. A flow chart will be used both during the operation and until extubation (depending which group the participant is in), to guide the fluid optimisation. All patients are continuously monitored for heart rate/rhythm, blood pressure and central venous pressure. This is recorded hourly on the Intensive Care charts. Fluid loss and urine output are also recorded and monitored closely. The addition of the ODM and its readings will be recorded on the same observation chart. Readings prior to and after fluid is given will be documented as will the type of fluid (blood or artificial plasma).

## Intervention Type
Procedure/Surgery

## Phase
Not Specified

## Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/10/2006

### Completion date
01/10/2007

## Eligibility

### Key inclusion criteria
Participants will be adult patients who are to undergo Coronary Artery Bypass Grafting (CABG) or valve surgery for the first time, both male and female. There will be a minimum of 21 participants in the pilot study. The small number is due to time constraints and the need for staff training. The participants will be randomly assigned to one of the three groups.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
21

### Key exclusion criteria
Patients who have had previous surgery will not be considered as they are at increased risk of complications due to a number of factors.

### Date of first enrolment
01/10/2006

### Date of final enrolment
01/10/2007

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**Royal Sussex County Hospital**
Brighton
United Kingdom
BN2 5BE

# Sponsor information

**Organisation**
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

**Sponsor details**
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Brighton and Sussex University Hospitals NHS Trust (UK)

# 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