

# Post-op oesophageal Doppler trial: effect on clinical outcome of extension of oesophageal Doppler goal-directed fluid optimisation into the post-operative recovery period

<b>Submission date</b> 12/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/09/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/05/2018	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cardiac output is the volume of blood pumped by the heart per minute. It can be measured by placing a probe into the oesophagus (food pipe) via the mouth or nose, a procedure called oesophageal Doppler monitoring. Guiding treatment with cardiac output monitoring has been shown to benefit patients undergoing major colorectal surgery, improving outcomes and reducing the length of hospital stay. Traditionally this monitoring has only been used during surgery. With the introduction of flexible probes, this monitoring can now be used in awake patients after surgery. The group most likely to benefit are high-risk patients. We aim to find out about the effect of continuing the use of this monitoring to guide treatment after surgery in high-risk colorectal surgery patients.

### Who can participate?

High-risk patients aged 18 and over undergoing colorectal surgery.

### What does the study involve?

Participants are randomly allocated to one of two groups. Participants in one group undergo oesophageal Doppler cardiac output monitoring for 16 hours (overnight) after their operation. Participants in the other group receive standard care with the probe in place but not used for monitoring. We then compare the outcomes of the two groups during their hospital stay and at follow-up.

### What are the possible benefits and risks of participating?

Oesophageal Doppler monitoring has already been tested in cardiac and trauma patients. Patients can request early removal of the probe before the end of the 16-hour monitoring period if they wish. Patients who may be at risk of nasal or oesophageal injury from the probe are excluded from the study.

Where is the study run from?  
St Thomas' Hospital (UK).

When is the study starting and how long is it expected to run for?  
May 2011 to October 2012

Who is funding the study?  
Guy's and St. Thomas' Charity (UK).

Who is the main contact?  
Mr Jonathan van Dellen  
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## Contact information

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Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

RJ1 11/N160

## **Study information**

### **Scientific Title**

Effect on clinical outcome of extension of oesophageal Doppler goal-directed fluid optimisation into the post-operative recovery period: a randomised control trial.

### **Study objectives**

Extension of OD-guided goal-directed fluid optimisation into the immediate 16-hour post-operative period, in high risk colorectal ERP patients, achieves an oxygen delivery index  $\geq 600$  ml /min/ m<sup>2</sup> for the majority of the duration of this period, and subsequently improves patient outcomes.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee London - Westminster, 06/04/2011, ref: 11/H0802/9

### **Study design**

Single-centre prospective single-blinded (assessor blinded to outcomes) randomised control study within an academic tertiary referral hospital setting

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

See additional files

### **Health condition(s) or problem(s) studied**

Improving perioperative care for elective colorectal surgery within an Enhanced Recovery Programme

### **Interventions**

Intervention group will have 16 hours post-operative oesophageal Doppler cardiac output monitoring with nurse-led stroke volume optimisation in an overnight intensive recovery (OIR) unit.

Control group will have an equivalent OIR admission without cardiac output monitoring (nasal oesophageal Doppler probe still in-situ for 16h measurements).

Follow-up of outcomes during hospital admission and standard telephone and outpatient clinic follow-up.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Post-operative length of stay (in days)

### **Secondary outcome measures**

1. Oxygen delivery index at end of 16h post-operative recovery period
2. Mean oxygen delivery index over 16h post-operative recovery period
3. Morbidity
4. Functional recovery (mobility and return of gastrointestinal function)
5. In-hospital and 30-day mortality

### **Overall study start date**

24/05/2011

### **Completion date**

01/10/2012

## **Eligibility**

### **Key inclusion criteria**

1. Consecutive elective or semi-elective patients due to undergo colorectal surgery as part of Enhanced Recovery Protocol involving resection or anastomosis of bowel
2. High-risk participants will be defined as having (1) pre-operative ASA grade III+ OR anaerobic threshold <11 ml/min/kg on cardiopulmonary exercise testing OR undergoing major complex surgery (as per OPCS 4.5 classification - Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures)
3. Ages 18 and over (no upper limit)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

86

**Key exclusion criteria**

1. Emergency surgery
2. Lack of capacity to consent
3. Pregnancy
4. Contraindications to oesophageal Doppler probe:
  - 4.1. Nasal injuries or polyps
  - 4.2. Severe oesophageal/laryngeal/pharyngeal disease
  - 4.3. Recent oesophageal/laryngeal/pharyngeal surgery
  - 4.4. Thoracic aortic aneurysm
  - 4.5. Severe bleeding diathesis
  - 4.6. Long-term systemic steroid therapy
  - 4.7. Portal hypertension

All excluded patients from patient groups to be reported in results

**Date of first enrolment**

24/05/2011

**Date of final enrolment**

20/09/2012

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St Thomas' Hospital**

London

United Kingdom

SE1 7EH

**Sponsor information**

**Organisation**

Guy's & St Thomas' NHS Foundation Trust (UK)

**Sponsor details**

c/o Karen Ignation  
London  
England  
United Kingdom  
SE1 7EH

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.guysandstthomas.nhs.uk/>

**ROR**

<https://ror.org/00j161312>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Guy's and St. Thomas' Charity (UK) ref: G100706

**Alternative Name(s)**

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

31/12/2018

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date. Current plans are for submission and storage with King's College London Data Management system.

## IPD sharing plan summary

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>				No	Yes
<a href="#">Protocol file</a>	version v1	14/10/2011		No	No