

# Comparison of outcomes of goal-directed fluid optimisation guided by LiDCOrapid and conventional oesophageal Doppler

<b>Submission date</b> 12/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input 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> 27/02/2018	<b>Condition category</b> Surgery	<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. Monitoring the cardiac output to guide fluid administration has been shown to benefit patients undergoing major colorectal surgery, improving their outcomes and reducing the length of hospital stay. The aim of this study is to detect any differences in patient outcome with the use of the LiDCOrapid monitor compared with conventional oesophageal Doppler monitoring.

### Who can participate?

Patients undergoing elective colorectal surgery.

### What does the study involve?

Both monitors are set up and the participant is randomly allocated to have their fluid administration guided by either LiDCOrapid or oesophageal Doppler. The anaesthetist is not able to see the measurements from the other monitor, but paired measurements are taken throughout. Patient outcomes are collected during their hospital stay and follow-up.

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

There is established evidence behind the use of both LiDCO and oesophageal Doppler monitoring and both are already in widespread use. An interim analysis will take place once half of the participants have been recruited to avoid harm if significant differences in outcome are detected.

### 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 2013

### Who is funding the study?

Guy's and St Thomas' Charity (UK)

Who are the main contacts?

Mr Jonathan van Dellen (Research Fellow) - [jvandellen@doctors.org.uk](mailto:jvandellen@doctors.org.uk)

Mr Andrew Williams (Consultant Colorectal Surgeon)

Dr Stuart McCorkell (Consultant Anaesthetist)

## Contact information

### Type(s)

Scientific

### Contact name

Mr Andrew Williams

### Contact details

Department of Colorectal Surgery

St. Thomas' Hospital

Guy's & St. Thomas' NHS Foundation Trust

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SE1 7EH

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RJ1 11/N160

## Study information

### Scientific Title

Comparison of goal-directed fluid optimisation guided by LiDCOrapid and conventional oesophageal Doppler effect on intra-operative oxygen delivery index and post-operative outcomes: a randomised control non-inferiority study

### Study objectives

Intra-operative goal-directed fluid optimisation guided by LiDCOrapid achieves non-inferior oxygen delivery index optimisation and equivalent patient outcomes compared to oesophageal Doppler monitoring.

### Ethics approval required

Old ethics approval format

Ethics approval(s)

**Study design**

Single-centre prospective double-blinded (patient & assessor) randomised non-inferiority 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**

Improving perioperative care for elective colorectal surgery

**Interventions**

Anaesthetist randomised to use either:

1. LiDCOrapid in intervention group OR
2. Conventional oesophageal Doppler cardiac output monitoring in control arm to guide goal-directed fluid therapy

Both monitors will be attached intraoperatively to allow paired readings. The anaesthetist will be blinded to the measurements of other monitor not being used.

**Intervention Type**

Device

**Primary outcome measure**

Post-operative length of stay (in days)

**Secondary outcome measures**

1. Intra-operative oxygen delivery index values
2. Intra-operative intravenous fluid volumes
3. Intra-operative differences in % change stroke volume
4. Morbidity
5. Functional recovery (mobility and return of gastrointestinal function)
6. In-hospital and 30-day mortality

**Overall study start date**

24/05/2011

**Completion date**

01/10/2013

## Eligibility

### Key inclusion criteria

1. Elective or semi-elective patients due to undergo colorectal surgery as part of Enhanced Recovery Protocol
2. Successful simultaneous LiDCOrapid and oesophageal Doppler monitoring throughout surgery

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

336

### Key exclusion criteria

1. Emergency surgery
2. Lack of capacity to consent
3. Pregnancy
4. All excluded patients from patient groups to be reported in results
5. Contraindications to oesophageal Doppler probe
  - 5.1. nasal injuries or polyps
  - 5.2. severe oesophageal/laryngeal/pharyngeal disease
  - 5.3. recent oesophageal/laryngeal/pharyngeal surgery
  - 5.4. thoracic aortic aneurysm
  - 5.5. severe bleeding diathesis
  - 5.6. long-term systemic steroid therapy
  - 5.7. portal hypertension
6. Contraindications to arterial line or LiDCOrapid
  - 6.1. weight <40kg
  - 6.2. aortic valve regurgitation

### Date of first enrolment

24/05/2011

### Date of final enrolment

01/10/2013

## 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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration