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

Submission date	**Recruitment status**	[_] Prospectively registered
12/07/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/09/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/05/2018	Digestive System	[_] 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?
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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
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 ≥600ml /min/ m2 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 anastamosis 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?
Participant information sheet				No	Yes
Protocol file	version v1	14/10/2011		No	No