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

Submission date 12/07/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/09/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/02/2018	**Condition category** Surgery	[_] Individual participant data [_] 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
Mr Andrew Williams (Consultant Colorectal Surgeon)
Dr Stuart McCorkell (Consultant Anaesthesist)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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)
NRES Committee London - Westminster, ref: 11/H0802/9

Study design
Single-centre prospective double-blinded (patient & assessor) randomised non-inferiority trial

Primary study design

Interventional

Study type(s)
Treatment

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(s)
Post-operative length of stay (in days)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's & St. Thomas' NHS Foundation Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration