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Cardiac Output Monitoring and Pre-operative Exercise Testing for Colorectal surgery

Submission date	Recruitment status	[ ] Prospectively registered
17/02/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2011	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Amongst patients having major elective colorectal surgery does intraoperative goal directed fluid therapy particularly decrease postoperative hospital length of stay in patients who are

categorised "high risk" on the basis of a preoperative cardiopulmonary exercise test result? - a double-blind parallel-arm randomised controlled single-centre trial

Acronym
COMPETE-C

Study objectives
Major colorectal surgery has traditionally been associated with a prolonged hospital stay and a moderate risk (1-5%) of mortality or serious cardiopulmonary morbidity.

Improved outcomes have been reported by international units and in NHS hospitals using a specific care bundle for major colorectal surgery: "Enhanced Recovery after Surgery" (ERAS). Such patient care pathways employ a multimodal approach to promote a rapid return to normal function. The Danish group around Kehlet, the originator of ERAS, claim that a hospital stay of 3 days or less for major colorectal surgery is now customary in their institutions whilst median stays using an ERAS approach of around 6 days have been produced elsewhere

Controversies exist regarding intraoperative fluid management for major colorectal surgery. In recent decades fluid restriction has been advocated, however such an approach uniformly applied risks bowel ischaemia and other complications.

Goal Directed Fluid therapy (GDT) refers to fluid management targeted toward improving the cardiac output to set levels, hence improving end organ perfusion. Minimally invasive devices are now available to measure cardiac stroke volume. Intra-operative GDT has been shown to reduce median hospital length of stay after major colorectal surgery from 9 to 7 days.

This study aims to determine whether goal directed fluid therapy gives additional benefit to patients undergoing surgery within an ERAS programme, and aims to address the controversies regarding fluid management.

As of 2007, Plymouth Hospitals NHS Trust provides a service to risk stratify patients undergoing elective surgery by Cardiopulmonary Exercise Testing (CPET), which can identify patients with a low cardiorespiratory reserve. These patients are at increased risk of complications after surgery. We have the capacity to perform CPET pre-operatively for all patients booked for elective major colonic or colorectal resection surgery. It may be that a subset of less fit patients may benefit more from GDT than a fitter cohort.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cornwall and Plymouth Research Ethics Committee, approved on 09/09/2008 (ref: 08/H0203 /159)

Study design
Double-blind parallel-arm randomised controlled single-centre trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Elective major colorectal surgery

Interventions
1. Cardiopulmonary Exercise Test (CPET)
The CPET test will be done in accordance with the consensus protocol from UK centre with reference to American Thoracic Society (ATS)/ American College of Chest Physicians (ACCP) recommendations. Anaerobic threshold will be determined by the V slope method with correlation with ventilatory equivalents.

2.Oesophageal Doppler monitoring (and Goal Directed Fluid Therapy)
All patients will receive oesophageal Doppler monitoring throughout the operation. This monitoring will be carried out by a trained investigator. Patients in the intervention group will be given warmed colloid (6% Hydroxyethyl starch) before surgical incision to reach GDT goals as per a predetermined protocol and have additional fluid boli administered as dictated by this algorithm until cessation of surgery.

The disposable oesophageal probe will be removed at the conclusion of surgery. The anaesthetist responsible for care will be blinded to the Doppler readings. The researcher carrying out the optimisation will be aware of all anaesthetic activity.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Amongst patients having major elective colorectal surgery under an Enhanced Recovery after Surgery (ERAS) pathway:
1. Does intraoperative goal directed fluid therapy decrease postoperative hospital length of stay when compared with standard therapy alone in patients who are categorised high risk on the basis of a preoperative cardiopulmonary exercise test result?
2. Does intraoperative goal directed fluid therapy decrease postoperative hospital length of stay when compared with standard therapy alone in patients who are categorised standard risk on the basis of a preoperative cardiopulmonary exercise test result?
3. Does intraoperative goal directed fluid therapy decrease postoperative hospital length of stay when compared with standard therapy alone in all patients?

Key secondary outcome(s))
Amongst patients having major elective colorectal surgery under an ERAS pathway, does intraoperative goal directed fluid therapy make a difference to the following when compared with standard therapy alone?:
1. Peri-operative mortality (30 days)
2. Postoperative hypotension
3. Postoperative fluid requirement
4. Return of gastrointestinal function
5. Tolerance of diet

Secondary outcomes 2-5 will be assessed every post-op day until the participants meet discharge criteria (median length of stay for this surgery is currently 9 days [as of 17/02/2009]).

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Both males and females, age 18 and older
2. Elective colorectal surgical patients scheduled for major surgery
3. Patients with a measurable anaerobic threshold (AT) above 8 ml O2/kg/min

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Absolute:
1. Unwillingness to participate
2. Inability to perform the tests and consent within the timetable for elective surgery
3. Measured Anaerobic Threshold below 8 ml O2/kg/min. Such patients will be considered to be extremely unfit and as such will not be suitable for inclusion in the trial.
4. Withdrawn by anaesthetist or surgeon
5. Acute myocardial infarction (35 days)
6. Unstable angina
7. Uncontrolled arrhythmias causing symptoms or haemodynamic compromise
8. Syncope
9. Active endocarditis
10. Acute myocarditis or pericarditis
11. Symptomatic severe aortic stenosis
12. Uncontrolled heart failure
13. Acute pulmonary embolus or pulmonary infarction
14. Thrombosis of lower extremities
15. Suspected dissecting aneurysm
16. Uncontrolled asthma
17. Pulmonary edema
18. Room air desaturation at rest <85%
19. Respiratory failure

20. Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (i.e. infection, renal failure, thyrotoxicosis)
21. Severe oesophageal disease
22. Recent oesophageal or upper airway surgery
23. Systemic steroid medication
24. Bleeding diathesis

Relative:
25. Left main coronary stenosis or its equivalent
26. Moderate stenotic valvular heart disease
27. Severe untreated arterial hypertension at rest (200 mm Hg systolic, 120 mm Hg diastolic)
28. Tachyarrhythmias or bradyarrhythmias
29. High-degree atrioventricular block
30. Hypertrophic cardiomyopathy
31. Significant pulmonary hypertension
32. Advanced or complicated pregnancy
33. Electrolyte abnormalities
34. Orthopaedic impairment that compromises exercise performance

Date of first enrolment
10/03/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Anaesthesia
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Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Other

Funder Name
Anaesthesia/ Association of Anaesthetists of Great Britain and Ireland (Ireland, UK) - Departmental project grant (main funding)

Funder Name
Plymouth Hospitals NHS Trust (UK) (ref: 08/H0203/159)

Funder Name
Fresenius Kabi UK (UK) - Unrestricted grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2012		Yes	No