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Colloid or crystalloid for goal directed fluid therapy in patients undergoing elective colorectal surgery

Submission date 17/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/12/2009	**Overall study status** Completed	
Last Edited 17/03/2014	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
YOR-A01243

Study information

Scientific Title
Colloid or crystalloid for goal directed fluid therapy in patients undergoing elective colorectal surgery: a randomised, double-blind controlled trial

Study objectives
Major surgery generates a strong systemic inflammatory response that in turn leads to an increase in oxygen demand in the peri-operative period. This substantial increase in oxygen demand is normally met by increases in the volume of blood that the heart pumps out each minute (cardiac output) and by increasing the amount of oxygen that the tissues extract from the blood. Most patients can meet this increased oxygen demand by increasing cardiac output and will usually do well after surgery. To increase cardiac output in an efficient way, i.e. by making the heart beat more powerfully rather than just faster, the patient needs to have an optimum amount of blood in their circulatory system. Recent studies have demonstrated that morbidity rates and length of stays in hospital can be improved by giving each individual patient just the right amount of intravenous fluid during their operation.

To date, no-one has proven in a randomised trial which type of intravenous fluid anaesthetists should be using to do this. Therefore we propose to carry out a randomised, blinded study looking into the differences between using crystalloid or colloid for perioperative haemodynamic optimisation in a population of medium to high risk patients having colorectal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (West) Research Ethics Committee approved on the 8th September 2009 (ref: 09/H1307 /77)

Study design
Single-centre randomised controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

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
Elective surgical resection of the colon

Interventions
Patients will receive either Volulyte™, a colloid in balanced salt solution or Hartmann's Solution for intra-operative haemodynamic optimisation guided by stroke volume variation. This will be given blinded as 250 ml boluses. Intervention will take place during the operation only. Follow up will be for 15 days or until hospital discharge.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Volulyte™, Hartmann's Solution

Primary outcome measure
Incidence of gastrointestinal morbidity on day 5 following surgery.

Secondary outcome measures
1. Incidence of post operative complications during hospital stay
2. Morbidity at 1, 3, 5, 8, 10 days measured by Postoperative Morbidity Survey
3. Length of stay in hospital after surgery
4. Recovery parameters (time to eating, drinking, and mobilising after surgery)
5. Peri-operative haemodynamic variables (central venous pressure [CVP], heart rate, blood pressure, oxygen delivery, stroke volume variation)
6. Cost effectiveness of the intervention
7. Measurement of inflammatory markers
8. Use of additional inotropic support
9. Use of "rescue colloid" boluses

Overall study start date
01/10/2009

Completion date
01/10/2011

Eligibility

Key inclusion criteria
Patients (both males and females) over 55 years of age undergoing elective colorectal surgery, who after routine cardiopulmonar exercise testing (CPET) at the Pre-assessment Clinic, have been found to have an oxygen uptake at anaerobic threshold (AT) less than or equal to 14.0 ml /kg/min as measured by the V-slope method.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
202

Key exclusion criteria
1. Patients less than 55 years of age
2. Patients having emergency procedures
3. Those who are American Society of Anaesthesiologists (ASA) classification grade 5
4. Patients who refuse or are unable to give informed consent
5. Renal failure with oliguria or anuria not related to hypovolaemia
6. Patients receiving dialysis treatment
7. Intracranial bleeding
8. Known hypersensitivity to hydroxyethyl starches or gelatins
9. Patients with sodium overload
10. Patients who have had inadequate time (less than 24 hours) to consider the Patient Information Leaflet
11. Patients with hypertrophic obstructive cardiomyopathy (HOCM), aortic stenosis, phaeochromocytoma, a low platelet count, or have used a monoamine oxidase inhibitor within the last 14 days

Date of first enrolment
01/10/2009

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
York Hospitals NHS Foundation Trust (UK)

Sponsor details
Wiggington Road
York
England
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Sponsor type
Hospital/treatment centre

Website
http://www.yorkhospitals.nhs.uk/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi (Germany) - Unrestricted research grant

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2014		Yes	No
HRA research summary			28/06/2023	No	No