

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

Submission date 17/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/03/2014	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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

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)

Primary study design

Interventional

Study design

Single-centre randomised controlled double-blind trial

Study type(s)

Not Specified

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(s)

Incidence of gastrointestinal morbidity on day 5 following surgery.

Key secondary outcome(s)

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

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 cardiopulmonary 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Department of Anaesthesia

York

United Kingdom

YO31 8HE

Sponsor information

Organisation

York Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/027e4g787>

Funder(s)

Funder type

Industry

Funder Name

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	01/02/2014		Yes	No
HRA research summary			28/06/2023	No	No