

Gelofusine® vs Geloplasma® in major abdominal surgery

Submission date 11/07/2008	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/07/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/04/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-005175-10

Study information

Scientific Title

Volume expansion using a balanced gelatin solution in patients undergoing major abdominal surgery

Study objectives

Null hypothesis: There is no difference in postoperative chloride levels between patients resuscitated with a balanced gelatin solution or a conventional non-balanced gelatin solution.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Awaiting approval by the Guy's and St Thomas' Research Ethics Committee as of 15/07/2008.

Study design

Prospective, randomised, double-blind study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Volume expansion during major abdominal surgery

Interventions

Patients will be managed perioperatively according to the enhanced recovery protocol, which is well established and constitutes routine practice for all patients undergoing major abdominal surgery at St Thomas' Hospital. Monitoring will be standard plus oesophageal Doppler in all cases. An arterial line will be sited in all patients, usually following induction of anaesthesia. A central venous line will be sited as clinically indicated, usually following induction of anaesthesia. A thoracic epidural will be sited at a level appropriate to the site of surgery. Anaesthesia will be induced as deemed appropriate by the anaesthetist, and maintained with volatile or propofol. Epidural or remifentanyl infusions will be used as deemed appropriate by the anaesthetist. This does not deviate from standard practice in our centre.

Colloid will be used intraoperatively to optimise stroke volume, as guided by parameters obtained by oesophageal Doppler.

Patients randomised to the balanced gelatin group will receive Geloplasma® (Fresenius) to optimise stroke volume. Patients randomised to the non-balanced group will receive Gelofusine® (B. Braun Medical Ltd) to optimise stroke volume. In both groups the colloid will be given as a discrete 250 ml bolus, and the change in stroke volume observed. If stroke volume shows a $\geq 10\%$ rise, the bolus will be repeated until no further rise ($\geq 10\%$) is observed. No further bolus will be given unless stroke volume falls.

Vasoconstrictors will be given if hypotension persists after optimisation of stroke volume. Inotropes will be considered if peak velocity is low and the clinical picture is suggestive of poor ventricular function. In both groups, additional crystalloid solution will be given to replace insensible loss, or as a solvent for drugs. Blood and clotting products will be given as deemed

appropriate by the anaesthetist. Patient temperature will be closely monitored and maintained using a fluid warmer and hot air blanket in all cases. The appropriate colloid will be given in recovery as volume expander as deemed appropriate by the anaesthetist.

Arterial blood samples will be obtained from the arterial cannula after induction of anaesthesia (immediately after insertion, before any colloid is given), at the end of surgery before cessation of controlled ventilation, on arrival in recovery, and after 2 hours in recovery. Presence of postoperative nausea and vomiting (and requirement for rescue antiemetics) will be recorded. Volume of colloid given during surgery will be recorded. Urinary sodium will be measured on insertion of the urinary catheter and after 2 hours in recovery.

Total duration of treatment and follow-up will be for the duration of the operation and for 2 hours in recovery.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gelofusine®, Geloplasma®

Primary outcome(s)

The following will be monitored during the surgery and two hours in recovery:

1. Postoperative chloride level
2. Postoperative base excess

Key secondary outcome(s)

The following will be recorded for the duration of surgery, and two hours in recovery:

1. Postoperative pH
2. Volume of colloid given
3. Postoperative renal function
4. Postoperative nausea and vomiting
5. Urinary Sodium
6. Urine output

Completion date

04/05/2009

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Both males and females
2. 18 years or over

3. Patients undergoing major abdominal surgery in the Enhanced Recovery After Surgery programme at Guy's and St Thomas' NHS Foundation Trust, UK

4. American Society of Anaesthesiologists (ASA) grade 1-3

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Known hypersensitivity to Gelofusine® or Geloplasma®
2. Oliguric or anuric renal dysfunction requiring dialysis
3. Estimated glomerular filtration rate (EGFR) <60 ml/min
4. Myocardial infarction within the previous 3 weeks
5. Heart failure (>New York Hearth Association [NYHA] class 2)
6. Liver insufficiency (aspartate aminotransferase >40 U/L, alanine aminotransferase >40 U/L)
7. Absence of written, informed consent

Date of first enrolment

04/02/2009

Date of final enrolment

04/05/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Guy's and St Thomas' Hospital NHS Foundation Trust

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust (UK)

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St Thomas' NHS Foundation Trust, Department of Anaesthesia (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration