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Gelofusine® vs Geloplasma® in major abdominal surgery

Submission date 11/07/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/07/2008	**Overall study status** Stopped	
Last Edited 17/04/2019	**Condition category** Surgery	

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
2008-005175-10

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 remifentanil 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 >=10% rise, the bolus will be repeated until no further rise (>=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 measure
The following will be monitored during the surgery and two hours in recovery:
1. Postoperative chloride level
2. Postoperative base excess

Secondary outcome measures
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

Overall study start date
04/02/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
England

United Kingdom

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)

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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.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

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