# Gelofusine® vs Geloplasma® in major abdominal surgery

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

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Stephen Tricklebank

## **Contact details**

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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)

## Sponsor details

R&D Department 3rd Floor Conybeare House Great Maze Pond London England United Kingdom SE1 9RT +44 20 7188 5736 Karen.Ignatian@gstt.nhs.uk

**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