# PHOENICS

## -Perioperative HES Trial

**P**rospective, randomized, controlled, double-blind, multi-centre, multinational study on the safety and efficacy of a 6% **H**ydroxyethyl starch (HES) s**O**lution versus an **E**lectrolyte solutio**N** **I**n patients undergoing ele**C**tive abdominal **S**urgery

## FAST FACTS

- Approximately 1-5 % of in-hospitalized patients suffer from renal failure postoperatively.
- Renal failure is known to increase length of hospital stay and mortality.

## MEDICAL PROBLEM

Hypovolaemia is a state of decreased or reduced circulating blood volume which can be caused by a number of medical events including blood loss during surgical interventions.

The aim of volume replacement is to compensate a reduction in the intravascular volume and to counteract hypovolaemia in order to maintain haemodynamics and vital functions.

There are controversies about which fluid should be used, colloids and/or crystalloids.

## OBJECTIVE

To investigate the safety and efficacy of a 6% Hydroxyethyl starch solution (HES 130) versus a balanced crystalloid solution in patients undergoing major elective abdominal surgery.

## BACKGROUND

Following publications of different investigator initiated trials comparing HES-containing solutions to crystalloids in critically ill patients, the European Medicines Agency (EMA), started procedures to analyse the benefits and risks of HES-containing solutions especially in those patients. As part of the outcome of these procedures, clinical trials in surgical and trauma patients were requested.

## OUTCOMES

### Primary endpoint:

Difference in mean eGFR using Cystatin C (day 1-3).

### Secondary endpoints:

Further safety (including coagulation, inflammation) and efficacy (including fluid balance, haemo-dynamics, vital signs, laboratory data) parameters.

## STUDY DESIGN

Prosepective, randomized, controlled, double-blind, parallel-group, multinational phase IV trial.

## SAMPLE SIZE & CENTRES

The study will recruit 2280 patients (i.e. 1140 per group).

Recruitment will be for a 2 years period and is planned to start end of 2016/ beginning of 2017.

Study duration will be 7 days. Follow-up will take place at day 28, day 90 and after 1 year post treatment.

Clinical study sites across Europe will be involved.

Participating countries will have a National Coordinator responsible for the conduct of this trial.

## INCLUSION & EXCLUSION CRITERIA

### Inclusion Criteria:

- Patients aged > 40 and ≤ 85 years of age.
- Patients undergoing elective abdominal surgery with an expected blood loss of ≥ 500 ml
- ASA physical status II – III
- Signed written informed consent form

### Exclusion Criteria:

- Weight ≥ 140 kg
- Renal impairment (defined as AKIN stage ≥ 1) or acute and/or chronic renal replacement therapy
- Contraindications of the investigational products (HES 130, electrolyte solution)
- Simultaneous participation in another interventional clinical trial

## STEERING COMMITTEE

A steering committee will be set up. Contact of the steering committee is the Chair of the ESA Research Committee;
Prof. Dr. W.F. Buhre (Netherlands).

## SPONSOR

The legal Sponsor is B. Braun, one of the world's leading providers and manufacturers of healthcare products including infusion therapy with fluid & volume replacement solutions. B. Braun is an industry partner of the ESA.

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SHARING EXPERTISE

The clinical trial will be performed in collaboration with Fresenius Kabi.

Fresenius Kabi is a global healthcare company that specialises in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. Fresenius Kabi is an industry partner of ESA.

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## CONTRACT RESEARCH ORGANISATION

The European Society of Anaesthesiology Clinical Trial Network is providing the infrastructure for this large European study.

## More Information

For further information please contact the ESA Research Department at research@esahq.org

European Society of Anaesthesiology ESA

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## CALL FOR CENTRES

Please contact research@esahq.org to receive the link to the study specific Call for Centre Form