Prospective, randomized, controlled, double-blind, multi-centre, multinational study on the safety and efficacy of a 6% Hydroxyethyl starch (HES) solution versus an Electrolyte solution in patients undergoing elective abdominal surgery.

**FAST FACTS**

- Approximately 1-5% of 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**

Prospective, 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).

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

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.

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.

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

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

WWW.ESAHQ.ORG/RESEARCH