



Prospective, randomized, controlled, double-blind, multi-centre, multinational study on the safety and efficacy of a 6% **H**ydroxyethyl starch (HES) **sO**lution versus an **E**lectrolyte solution **N** in patients undergoing ele**C**tive abdominal **S**urgery

## 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) had 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.

# PHOENICS

-Perioperative HES Trial-



PHOENICS



Clinical Trial Network



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## OUTCOMES

**Primary endpoint:**

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

**Secondary endpoints:**

Further safety and efficacy parameters (e.g. renal function, coagulation, inflammation, composite of mortality and major post-operative complications, fluid balance, haemodynamics/vital signs, laboratory data).

## STUDY DESIGN

Prospective, randomized, controlled, double-blind, parallel-group, multinational phase III/IV trial.

Main duration will be up to 90 days after surgery. Follow-up call will take place 1 year post treatment.

## SAMPLE SIZE & CENTRES

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

The study is currently ongoing.

Clinical study sites across Europe (Belgium, Czech Republic, France, Germany, the Netherlands, Poland, Spain) are involved.

Austria, Croatia, Romania and Serbia will most probably be involved.

Participating countries 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 chronic) or acute and/or chronic renal replacement therapy
- Hyperkalaemia
- Contraindications of the investigational products (HES 130, electrolyte solution)
- Simultaneous participation in another interventional clinical trial

## STEERING COMMITTEE

Contact of the steering committee is the Chief Investigator of the trial, Prof. Dr. W. F. Buhre (the Netherlands).

## SPONSOR

The legal Sponsor is Fresenius Kabi, a global healthcare company that specialises in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. Fresenius Kabi's products and services are used to help care for critically and chronically ill patients. Fresenius Kabi is an industry partner of the ESA.



The clinical trial is performed in collaboration with B. Braun Melsungen AG. B. Braun is one of the world's leading providers and manufacturers of healthcare solutions today.



## CONTRACT RESEARCH ORGANISATION

The European Society of Anaesthesiology Clinical Trial Network is acting as Academic-CRO for this large European trial and is supported by PRA Health Science.

## More Information

For further information please contact the ESA Research Department at [ctn-cro@esahq.org](mailto:ctn-cro@esahq.org)



[WWW.ESAHQ.ORG/RESEARCH](http://WWW.ESAHQ.ORG/RESEARCH)

## CALL FOR CENTRES

Please contact [ctn-cro@esahq.org](mailto:ctn-cro@esahq.org) to receive the link to the study specific Call for Centre Form