



Pragmatic, 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 trauma patients

FAST FACTS

- Trauma is one of the major health care issues.
- Worldwide trauma results in more than 5 Mio deaths.

MEDICAL PROBLEM

Volume resuscitation is an essential part of the initial management of trauma patients. There are controversies about which volume should be used, colloids and/or crystalloids. During pre-hospital care the treatment addresses the acute traumatic injury including volume resuscitation and administering medications in order to control bleeding. Thereafter the focus changes from damage control resuscitation to goal-directed volume administration in order to establish and maintain adequate tissue perfusion and oxygenation.

OBJECTIVE

To investigate the safety and efficacy of a 6% Hydroxyethyl starch solution (HES 130) versus a balanced crystalloid solution in trauma patients.

Trauma is one cause of morbidity and mortality. Renal failure, sepsis and septic shock are some examples for complications following trauma.

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

TETHYS

-Trauma HES Trial-



trials in surgical and trauma patients were requested.

OUTCOMES

Primary endpoint:

Composite endpoint of 90 day mortality and 90 day renal failure any time during the first 3 months.

Secondary endpoints:

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

STUDY DESIGN

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

SAMPLE SIZE & CENTRES

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

The study aims to recruit maximum 350 patients in this period.

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 > 18 and ≤ 80 years of age
- Patients with blunt or penetrating trauma suffering from estimated blood loss of ≥ 500 ml
- Initial surgery planned within 24 hrs after trauma
- No signs of intracranial or cerebral haemorrhage
- Base excess < - 4 mEq/l



Administration of less than 15 ml/kg body weight colloid between trauma injury and hospital admission.

- Signed written informed consent form or as locally required

Exclusion Criteria:

- Weight ≥ 140 kg
- Patients expected to die within 24h after traumatic injury
- Renal impairment (defined as AKIN stage ≥ 1) or acute and/ or chronic renal replacement therapy
- Severe coagulopathy (defined as INR > 1.2)
- 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.



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.

More Information

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



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