



TETHYS

-Trauma HES Trial-



Clinical Trial Network



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 fluid should be used, colloids and/or crystalloids.

During pre-hospital care the treatment addresses the acute traumatic injury including fluid resuscitation and administering medications in order to control bleeding. Thereafter the focus changes from damage control resuscitation to goal-directed fluid 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 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), 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.

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 (e.g. renal function, coagulation, inflammation, adverse events) and efficacy (e.g. fluid balance, haemodynamics/vital signs, laboratory data) parameters.

STUDY DESIGN

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

SAMPLE SIZE & CENTRES

The study will recruit at least 218 patients (i.e. 109 per group). Recruitment started in February 2019. Clinical study sites across Europe (e.g. Belgium, France, Germany, Spain, the Netherlands) and in South Africa are involved.

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



INCLUSION & EXCLUSION CRITERIA

Inclusion Criteria:

- Patients aged ≥ 18
- Patients with blunt or penetrating trauma suffering from estimated blood loss of ≥ 500 ml
- Initial surgery deemed necessary within 24 hrs after trauma

- No signs of intracranial or cerebral haemorrhage
- Administration of less than 15 ml/kg body weight colloid between trauma injury and hospital admission
- Deferred 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 chronic) or acute and/ or chronic renal replacement therapy
- Hyperkalaemia
- Severe coagulopathy
- 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 pragmatic multinational trial and is supported by PRA Health Science and TCD Global.

More Information

For further information please contact the ESA Research Department at ctn-cro@esahq.org



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