



## **Prospective, controlled, single-blind, bicentric, randomized study on the safety of HES 130/0.42 combined with a balanced electrolyte solution vs. 5% albumin combined with an unbalanced electrolyte solution (NaCl 0.9%) in patients with compensated renal failure**

B. Braun Melsungen AG, Hospital Care, Clinical Development

**Background:** Hydroxyethylstarch (HES) is the most intensively studied artificial colloid and various HES preparations exist showing different physico-chemical properties. The majority of hydroxyethylstarch preparations (HES) found in clinical use contain 0.9 % NaCl (sodium chloride = physiological saline solution) as a “carrier” for the colloid component. It has been long known that infusion of physiological saline solutions may increase the plasma chloride concentration to higher extend than the sodium concentration. In order to avoid such electrolyte imbalances a HES solution with a balanced electrolyte solution (i.e. the crystalloid component of the HES solution is adapted to physiological plasma electrolyte concentrations) as carrier was developed.

**Methods:** The study is a prospective, controlled, single-blind, bicentric, randomized clinical investigation in patients with compensated renal failure. The anticipated number of patients is 52 adult patients, randomly assigned to one of the following groups: Tetraspan 6% combined with Sterofundin ISO or Albumin 5% combined with NaCl 0.9%. The primary objective of the study is to investigate the impact of two different volume replacement therapy regimes in patients with reduced renal function (i.e. 1.5 mg/dl < serum creatinine < 3.0 mg/dl) in terms of safety, i.e. the acid-base balance. The aim is to show differences between the two regimes with superiority of the balanced regime.

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**Status:** Study terminated due to organizational reasons at the study sites: low recruitment

**Sponsor:** B. Braun Melsungen AG

**Register:**

<http://clinicaltrials.gov/ct2/show/NCT00936247?term=hes&spons=braun&rank=3>