



## Evaluation on the safety profile of Venofundin® 6% and Tetraspan® 6% in the Asian-Pacific Region

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**Background:** Following the recent registration of Venofundin® 6% and Tetraspan® 6% in the Asian-Pacific region the present study designed as a post-authorisation observational (non-interventional) study is proposed in order to build up a safety database in the population of the Asian-Pacific region.

**Methods:** This is a prospective, multicentric, international, non-interventional (observational) post-authorisation safety study. The study includes male and female patients who undergo elective surgery with ASA-class  $\leq$  III and who are scheduled to receive HES 130/0.42 (Venofundin® 6% or Tetraspan® 6%) for perioperative plasma volume replacement therapy. The administration of HES 130/0.42 is determined by the respective summary of product characteristics. The primary objective is to investigate on the frequency of adverse drug reactions. Secondary objectives are based on routinely measured clinical and laboratory parameters (e. g. haemodynamics, blood coagulation, electrolytes, blood gas analysis, use of blood products). At least 1000 patients will be documented in order to identify adverse reaction which occur with a frequency of at least 0.3% with the option to recruit maximally up to 1500 patients which allows the detection of adverse reactions with 0.2% frequency. An interim analysis after about 300 patients enables to detect an adverse drug reaction with an occurrence of 1%.

**Principal investigator:** Anaesthesiology departments of hospitals in China and Malaysia

**Status:** Recruitment started in 12/2008

**Sponsor:** B. Braun Melsungen AG