



Perioperative Blood Volume Changes Caused by Hemorrhage and Fluid Therapy During Urologic Surgery

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Background: HES 130/0.42 has a number of proven and potential benefits over the starch solution HES 200/0.5 which has been used for a long time. The accumulation of the substance in the plasma and tissue is low even under high doses or repeated administration. Because of the plasma half-life and the resulting rapid clearance, the controllability is very good. Due to the plasma half-life, duration and extent of the volume efficiency of HES 130/0.42 seems to be shorter and smaller than those of HES 200/0.5, especially in major operations and surgical procedures with high fluid requirements. The objective of this study was to prove that equivalent doses of HES 130/0.42 and HES 200/0.5 are required to maintain normovolemia and hemodynamic stability and to obtain clinical and laboratory safety parameters.

Methods: This is a prospective, randomized, double-blind, monocentric parallel group comparison of a clinical phase III study to demonstrate the equivalence of HES 130/0.42 to HES 200/0.5. 100 patients (between 18 and 80 years of age) are randomly assigned to one of the following groups: 6% Venofundin 130/0.42 or 6% Infukoll® 200/0.5. The primary endpoint of the study was the total volume of study medication administered from start of treatment to the end of the day of operation (24:00).

Results: A total of 88 male and 12 female patients (median age 66 years; range: 38-80) were enrolled into the study, 50 each in group HES 130/0.42 and HES 200/0.5. The majority of patients suffered from prostatic carcinoma, followed by urinary bladder tumour and various other diagnoses. As the study results show, a comparison of the two study medications establishes comparable hemodynamic stability in both treatment groups with regard to the median duration of observation (HES 130/0.42: 16.08 h; HES 200/0.5: 16.08 h), median duration of surgery (HES 130/0.42: 2.83 h; HES 200/0.5: 2.95 h), and median duration of ICU stay (HES 130/0.42: 11.08 h; HES 200/0.5: 10.67 h). The tolerability of both substances was very good. The doses of both HES were equivalent during surgery (HES 130/0.42: 1150±574 mL versus HES 200/0.5: 1070±572 mL; p=0.0002) and during ICU stay (1390±955 mL versus 1245±715 mL; p=0.0196), but for the whole observation period, equivalence could not be demonstrated statistically (HES 130/0.42: 2540±1232 mL vs HES 200/0.5: 2290±1040 mL; p=0.1379).

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