Premature termination of a Clinical Trial

Full title of the clinical Trial:

Plasma Pharmacokinetics of Prophylactic Cefazolin Administered for Cardiac Surgery: Comparison of Cardiopulmonary Bypass Priming with Additive Human Albumin 20% vs.Pure Crystalloid Priming: A single center, prospective, randomized and controlled trial

Blutplasma Konzentrationen von prophylaktischem Antibiotikum (Cefazolin) während herzchirurgischen Eingriffen: Einfluss von Albumingabe im Vergleich zur Standard-Primingfüllung der Herz-Lungen-Maschine: Eine monozentrische, prospektive, randomisierte und kontrollierte Studie

EudraCT Number: 2020-002756-21

Sponsor: Medical University of Vienna
Represented by (name): Univ.Prof.Dr. Edda Tschernko

Reason for premature termination of the clinical trial:

Pre-planned interim analysis showed under-powering even if full investigational number would be pursued. Therefore, the trial was terminated early.

Study results (if available):

Overall, the mean concentration of total Cefazolin was higher in the intervention group (159 µg/mL, SD ± 83.71) compared to the mean concentration in the control group (121.2 µg/mL, SD±75.84) ($p>0.05$). Total concentrations of Cefazolin dropped by 19,9 % in the control group (176.7 µg/mL SD ± 30.52 vs. 159.8 µg/mL SD ± 29.25) and by 16,2% in the intervention group ($p>0.05$) after CPB. Unbound Cefazolin concentrations dropped by 27.7 % and by 20.4% after beginning CPB (intervention 118.6 µg/mL SD ± 25 vs. control 149.9 µg/mL SD ± 33.1) ($p>0.05$). Although not statistically significant, the concentration of total Cefazolin was increased in the intervention group. We could not show that there was a substantial difference between the two groups in unbound Cefazolin concentrations. Therefore, the higher total concentration might result from increased albumin-bound cefazolin concentrations.

Higher albumin-bound antibiotic concentrations might be beneficial to prolong the time over the break point concentrations for Cefazolin and ultimately decrease surgical site infections.

Date and Signature of Sponsor representative: