



Premature termination of a Clinical Trial

Full title of the clinical Trial: Development of intravascular microdialysis as a tool for therapeutic drug monitoring in children.

EudraCT Number: 2018-000010-38

Sponsor: Medical University of Vienna

Represented by (name): Zeitlinger Markus, Ass.Prof.Priv.Doiz.Dr.

Reason for premature termination of the clinical trial:

Although the results from the first cohort (healthy male volunteers) were promising, it was decided that the present study design was not appropriate to start the next cohort (children).

Study results (if available):

Experiment A (physiological saline) yielded mean values (\pm standard deviation) of 28.6% (\pm 1.0%) and 13.4% (\pm 2.7%) for recovery (forward dialysis) and loss (retrodialysis), respectively. Because of the marked difference between forward and retrodialysis and the low rates of recovery/loss, the experiments were modified by adding human albumin 1% to the perfusion solution (experiment B). In these experiments the mean recovery (\pm standard deviation) during forward dialysis was 52.7% (\pm 3.8%) and the mean loss during retrodialysis was 45.8% (\pm 4.0%). In experiment B values for recovery/loss were similar between the sampling-intervals and in both directions (between retrodialysis and forward dialysis). Therefore, this experimental setting of experiment B was chosen for the calibration in the subsequent in vivo part of the study.

Study population: 10 healthy male volunteers; the mean age was 27.3 ± 5.1 years and mean weight 75.5 ± 6.4 kg.

Details can be found in the attached publication.

Date and Signature of Sponsor representative:

23. MAI 2023 