



## 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  $27.3 \pm 5.1$  years and mean weight  $75.5 \pm 6.4$  kg.

Details can be found in the attached publication.

**Date and Signature of Sponsor representative:**

23. MAI 2023  
