Statistical plan: The effect of blood pressure on cerebral blood flow in comatose out-of-hospital cardiac arrest patients

Brief Title: Blood pressure and cerebral blood flow after cardiac arrest

Official Title: The effect of blood pressure on cerebral blood flow in comatose out-of-hospital cardiac arrest patients

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Statistical plan

Trial size
The minimal clinically important difference in internal carotid artery blood flow between evaluations at MAP 65 and 95 mmHg is estimated to be 15%. A power calculation indicated that at least 16 patients were required to detect a difference in internal carotid artery blood flow of 15% corresponding to about 24 ml/min with a standard deviation for the change of 31 ml/min in order to obtain a 5% significance level and a power of 80%. We plan to include 20 patients.

Statistical analysis
Analysis of the time points at MAP 65, 80, and 95 mmHg is by a repeated measure mixed model, fit by restricted maximum likelihood in a structured covariance model with intervention (MAP 65, 80, and 95 mmHg) as a fixed effect, and the individual variable as a random effect to account for the within-individual correlation of the data (Proc mixed; SAS 9.4, SAS Institute, Cary, NC, USA). If the overall effect of the intervention is significant, the changes between the levels of MAP will be evaluated with correction for multiple testing by the Tukey–Kramer Test for Post Hoc Analysis. Analysis of variables not normally distributed is after logarithmic transformation in order to obtain a normal distribution or by a Friedman test and if the test is significant changes are evaluated using Wilcoxon signed rank sum test with correction for multiple testing by the Tukey–Kramer Test for Post Hoc Analysis. Values are presented as mean ± SD or median with interquartile range for not normally distributed data and statistical significance is set at $P < 0.05$. Figures are drawn in R for Windows (version 3.4.1) using the package ggplot2.