COVER PAGE

Official title: Evaluation of lipid emulsion on GCX in critically ill patients.

NTC number: NCT03216850

Date of the document: 7. 11. 2019

Objective: To assess the influence of lipid emulsion on EG integrity in ICU patients using video microscopic and biochemical methods.

Design: Prospective observational single centre study.

Methods: Patients in surgical ICU after major abdominal surgery or cardio surgery and in general ICU were assessed for eligibility for this pilot observational study in University Hospital. The study was performed during the first day of adding lipids as a part of their PN. The patients were given the SMOFlipid 20% for 6 hours in prescribed dose of approx. 1g/kg of body weight. EG integrity was measured indirectly by automated sublingual video microscopy calculating a parameter PBR which describes the amount of lateral deviation of red blood cells from the central column and by levels of syndecan-1 and syndecan-4 in plasma as EG degradational products. Measurements were performed before lipid administration (T0) and 30 minutes after (T6) the infusion of lipid emulsion was completed.

Scientific background: Endothelial glycocalyx (EG) is a carbohydrate-rich vascular lining of the apical surface of endothelial cells. It has been proved to have an essential role in vascular homeostasis. Lipid emulsions as part of parenteral nutrition (PN) are widely used in patients in the setting of critical care and perioperative medicine. Due to their structure, lipids may potentially interact with EG. The aim of the study was to evaluate the effect of lipid emulsion on EG.

Statistical considerations: The study was designed as a pilot prospective observational and feasibility study because there were no existing data regarding the methodical approach to glycocalyx assessment after exposure to lipid emulsion in clinical settings. We planned to enrol in the pilot study 15 patients, such sample size was deemed to be sufficient to obtain pilot data for hypothesis verification. Results were summarized using descriptive statistics and presented as mean (SD) for continuous variables, and as median (IQR) for non-normally distributed data. Shapiro-Wilk test was used for normality tests, Student´s paired t-tests were used to test the difference between parameters obtained at T0 and T6 time points. Pearson correlation and Spearman rank order correlation analysis were performed to test the relationship between PBR values and soluble fraction of syndecans-1 and syndecan-4. The level of significance was set at $p < 0.05$. MedCalc 7.6.0. (MedCalc Software, Ostend, Belgium) and Prism 5 for Mac OS X (Version 5. Ob, December 19, 2008) was used for statistical analysis.

Chief Investigator: Vladimir Cerny

Name of site: Hradec Kralove