

Statistical Analysis Plan

Development of Pneumonia Due to Alveolar Glucose Levels in Systemic Hyperglycemia

Version: 1

Date: 08/01/2017

Sample size calculation:

The sample size estimate was based on the assumption that in the investigated patient population the occurrence of pneumonia could be expected in 10% of the patients. Thus, for an unconnected sample, a ratio (m) of 0.9 controls per incidence of pneumonia. In a previous study (Bacterial respiratory tract infections are promoted by systemic hyperglycemia after severe burn injury in pediatric patients, Kraft et al., Burns, 2014, May), it was found that the mean values (δ) of both groups for glucose differed by about 30 mg / dL in the mean with a standard deviation (σ) of 20 mg / dL. Under the same conditions, 14 controls and 16 patients with pneumonia are needed to reject the null hypothesis with a probability (power) of 0.9.

The occurrence of the first type error (α) was set at 0.01. Design: Independent

$\alpha = 0.01$; power = 0.9; $\delta = 30$; $\sigma = 20$; $m = 0.9$; $n = 16$;

t-test confidence interval width = 40.68604

Calculated with PS Power and SampleSize Calculator Version 3.0,
<http://biostat.mc.vanderbilt.edu/PowerSampleSize>

Documentation / Evaluation:

All study-relevant data are recorded in the provided documentation sheets by the responsible study physicians and, if necessary, the study assistants. The study forms are digitized and stored in the in-house EDP system in compliance with the safety guidelines using the programs Microsoft Excel® and Access®. Radiological images are stored in digital form, preferably in TIFF or raw data format. The statistical analysis is carried out by means of the programs Sigmaplot® and Sigmaplot®.

The statistical evaluation is carried out on the one hand with regard to the cut-off value of the glucose threshold of the lung by means of Receiver Operating Characteristic (ROC). This is used to validate our findings in comparison to the already existing preliminary studies. The evaluation of dichotomous variables is performed by Chi Square Test or, if necessary, by Logistic Regression Analysis. Constant features are compared using Student's t-test, analysis of variance between the groups. With regard to the presence of disturbing variables between the two groups, the formation of subgroups, possibly a matching by means of a propensity score, is planned.