Statistical Analysis Plan

Determination of the Predictors of Nocturnal Desaturation in Postpartum Women

Primary Objective

- To investigate the effect of the method of delivery (vaginal delivery vs. cesarean section) on oxygen saturation in the first postpartum night. The primary hypothesis is that nocturnal desaturation occurs more frequently in cesarean section compared with vaginal delivery.

Secondary Objectives

- To evaluate the effect of upper body position during sleep (45 degree elevated vs. nonelevated) on oxygen saturation in the first postpartum night. The secondary hypothesis is that an upper body position elevated by 45 degress is associated with a lower frequency of nocturnal desaturation.

Outcomes

- The primary outcome is duration of SpO2 below 90%. The secondary outcomes are Oxygen Desaturation Index (ODI, defined as number of oxygen desaturations by at least 3 % per hour, pulse rate, mean and minimum SpO2).

Statistical Methods

- All analyses will be performed with pre-specified endpoints and statistical methods. The primary and secondary aim will be studied using Wilcoxon rank-sum tests for continuous variables with non-normal distribution. As an a priori defined subgroup analysis we will assess the effect of the sleeping position on the primary outcome in subgroups stratified by delivery route. Statistical analyses will be performed with Stata (StataCorp) and SPSS (IBM Inc.) Japan, Tokyo, Japan). A two-tailed p-value of <0.05 will be regarded as statistically significant.