UNIVERSITY OF SÃO PAULO
SÃO PAULO MEDICAL SCHOOL

STATISTICAL ANALYSIS PLAN

Official Title of the Study:

Safety and Effectiveness of Different Interface Models for Non-Invasive Ventilation Support in Preterm Infants with a Gestational Age of 28 Weeks or Greater

NCT Number:	NCT Pending
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Principal Investigator / Author:	André Luis Bispo Neves Master's Research Project in Child Health
Advisor / Co-Investigator:	Prof. Cintia Johnston, Ph.D.

This document contains official study protocol/statistical analysis information submitted to ClinicalTrials.gov in accordance with 42 CFR 11.48 and ClinicalTrials.gov Results Data Element Definitions.

Statistical Analysis Plan

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Demographic characteristics and variables, as well as pain scores, behavioral status, and respiratory discomfort, will be described according to frequencies and analyzed using Student's t-test (if showing a normal distribution) or the Wilcoxon/Mann-Whitney test. Frequencies will be compared using the Chi-square test.

Measures of central tendency (mean or median) and dispersion (percentiles, standard deviation) will be calculated for continuous variables. Normality will be assessed using the Shapiro-Wilk or Kolmogorov-Smirnov methods.

Analyses will be conducted to verify the association or correlation between the scores obtained and the outcomes under analysis (length of hospital stay and NICU stay; PIVH, mortality). Repeated assessment measures will be compared between groups using the Friedman test, and may be evaluated in relation to the outcomes using GEE (Generalized Estimating Equations).

Multiple logistic regression will be used to identify potential predictors of success or failure of NIV, calculating odds ratios with 95% confidence intervals (CI). The variables selected for multivariate analysis will be those that correspond to p-values less than 0.1 in the univariate analysis.

Data tabulation will be performed using Microsoft Excel® version 2010, and statistical analyses will be conducted using The Statistical Package for the Social Sciences (SPSS®) version 20.0. Results are presented as mean, standard deviation, absolute frequency, median, minimum, and maximum. Considered statistically significant when $p \leq 0.05$.