STUDY PROTOCOL

Auto-PAP for pulmonary hypertension treatment in decompensated heart failure patients with obstructive sleep apnea (ASAP-HF): A two center pilot study

Study Number: ASAP-HF

NCT02963597

Version: Version 1.3 Final

Date: 30 May 2017

Principal Investigator: Sunil Sharma MD, FAASM
Chair, Division of Pulmonary and Critical Care
Director of Pulmonary Hypertension Program
Einstein Medical Center, Philadelphia, PA

Statistical Methods

Baseline characteristics, medical history and ApneaLink parameters were collected and compared between treatment groups. Descriptive statistics, including mean, SD, median and quartiles were presented for each group. A two-sided test was used to compare means for continuous parameters, and a Fisher's Exact test was used to compare proportions for categorical parameters.

The primary study objective was to compare the PAP intervention arm and the standard of care arm specifically to the change in pulmonary pressures from baseline to 48 hours post-treatment. Secondary objectives involved comparison of the change from baseline to 48 hours for the following parameters: 6-minute walk distance (6MWD), NT pro-BNP and echocardiographic measures. Descriptive statistics were generated at Baseline and 48-hours for each group and the paired mean/median change for each parameter was compared between treatment groups using an exact Wilcoxon test.

All statistical comparisons of treatment groups were generated using a two-sided significance level of 0.05. Statistical software, SAS®, Version 9.4, was used for all analyses.