Effect of the adjunction of the Double Trunk Mask above standard nasal cannula during acute hypoxia

5 March 2018

Statistical Analysis

All participants who received this intervention and completed two phases of study were included in the efficacy analysis.

A sample size of 20 participants was needed to provide 90% power to detect a 10 mm Hg difference in PaO2. ANOVA for repeated measures followed by a post hoc test was used to compare the difference between participants receiving (Nasal Cannula + Double Trunk Mask) and Nasal Cannula alone.

The test was performed with a significance level of 0.05 (two-sided). Statistical analyses were carried out using SigmaPlot software version 11.0 (Systat Software Inc. UK).

Adverse Event Assessment

Safety was assessed by the number of participants with adverse events (AEs). AEs were collected by systematic assessment using terms from the Medical Dictionary for Regulatory Activities (MedDRA), version 11.1 in participants who received one or more doses of intervention. Adverse events during washout were not collected.

Figure 1