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

5 March 2018

Study Protocol and Statistical Analysis Plan

Study Design

This is a single-center, randomized, blind investigator, 2-way crossover study design. Enrolled participants had hypoxia being treated at Intensive Care Unit associated with a hospital in Hornu (Epicura).

The study consisted of two intervention periods separated by a washout period of 30 minutes. (Figure 1)

The objective of the study is to determine whether adjunctive mask of our design (Double Trunk Mask - DTM) has an effect on increasing arterial pressure in Oxygen (PaO2) diagnosed with hypoxia.

The protocol and informed consent documents were reviewed and approved by a recognized ethics review board at the study facility. The study was performed in accordance with the Declaration of Helsinki.

Participants

Inclusion Criteria:

Regardless of gender, at least 18 years of age and diagnosed with Hypoxia ($PaO_2/FiO_2 < 380$ mm Hg), dyspnea, respiratory rate (RR) ≥ 25 CPM, $PaCO_2 \leq 45$ mmHg, patient with an arterial catheter and without hemodynamic instability, Glasgow Coma Scale ≥ 12/15, written consent. Participants were also required to have a sufficient level of education to understand study procedures and be able to communicate with site personnel.

Exclusion Criteria

Patients were excluded if they Hypercapnia (> 45 mm Hg with respiratory acidosis), COPD, pulmonary fibrosis, hypoventilation obesity syndrome, arterial pressure < 60 mm Hg or treatment by epinephrine > to 0,1 gamma/kg/minute, deterioration of awareness (Glasgow scale < or = 12), acute confusional state.

Participants were randomized in a 1:1 ratio to receive either classical oxygenation with nasal cannula (NC) for 20 minutes or NC with an adjunctive of a Double Trunk Mask.

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Primary Endpoints

The primary endpoint was the change of PaO2.

Sequence (Figure 1): The patient should be placed in semi-seated (position at 45 °)

Patient will be oxygenated with classical nasal cannula. Oxygen flow rate will be adjusted to obtain a Saturation in oxygen > at 90%.

1. Arterial gazometry will be taken after 20 and 60 minutes with NC.
2. The clinician will associate the Double Trunk Mask (DTM) with the same parameters of the nasal cannula. Arterial gazometry will be performed after 20 and 60minutes after placement of DTM.
3. After the withdrawal of DTM, arterial gazometry will be performed after 20 and 60 minutes

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 will be using to compare the difference between participants receiving (CN + DTM) and CN alone.

The test was performed with a significance level of 0.05 (two-sided). Statistical analyses were carried out using SigmaPlot software version 12.0 (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

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