

Clinical Intervention Study Protocol

FULL PROTOCOL TITLE

Effect of a Modified Oxygen Mask Associated to Nasal Prongs During High Flow Oxygenation in ICU patient: a cross over study

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PRÉCIS

Study Title

Effect of a Modified Oxygen Mask Associated to Nasal Prongs During High Flow Oxygenation in ICU patient: a cross over study

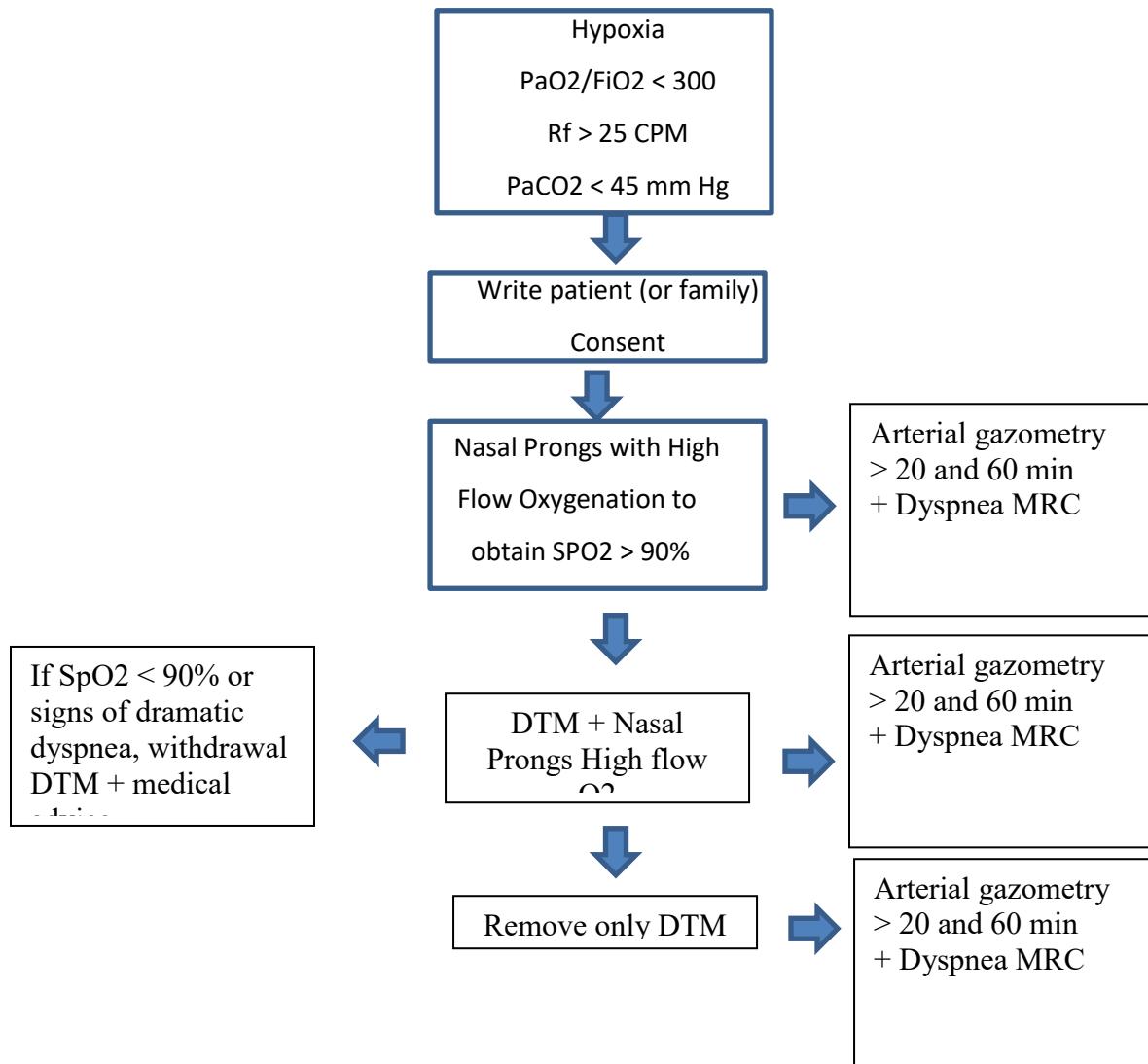
Objectives

The primary endpoint was the change of PaO2.

The secondary endpoint was the change of PaCO2, pH and patient respiratory comfort

Design and Outcomes

This is a single-center, randomized, blind investigator, 2-way crossover study design to test the efficacy of a special mask (DTM) add above nasal prongs during High Flow Oxygenation

**Figure 1**

Interventions and Duration

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

Patient will be oxygenated with high-flow nasal cannula (HFNC). Fraction delivered in Oxygen and 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 HFNC.
2. The clinician will associate the Double Trunk Mask (DTM) with the same parameters of the high-flow nasal cannula. Arterial gazometry will be performed after 20 and 60 minutes after placement of DTM.
3. After the withdrawal of DTM, arterial gazometry will be performed after 20 and 60 minutes

Sample Size and Population

Enrolled participants had severe hypoxia being treated at Intensive Care Unit

1. STUDY OBJECTIVES

1.1 Primary Objective

The experimental treatment will result of an increase of PaO2 when the special mask will be adding above nasal prongs compared with no mask addition.

1.2 Secondary Objectives

The Secondary objectives is the change of PaCO2, pH and patient respiratory comfort with the mask addition above prongs

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Oxygen therapy is the main treatment during Hypoxia. In this case, arterial Pressure Oxygenation should be maintained within strict limits. High Flow Oxygenation system can be used to administer Oxygen therapy (FDO2). In this case, high inspiratory flow decreases fraction delivered in oxygen. The addition of a special mask (Double Trunk Mask) can limits the fraction delivered in oxygen decrease.

2.2 Study Rationale

Few studies emphasize the decreases of FDO2 during inspiratory flow increases.

Studies:

Hnatiuk OW, Moores LK, Thompson JC, Jones MD. Delivery of high concentrations of inspired oxygen via Tusk mask. Crit Care Med. 1998 Jun;26(6):1032-5. PubMed ID: 9635651

Chechani V, Scott G, Burnham B, Knight L. Modification of an aerosol mask to provide high concentrations of oxygen in the inspired air. Comparison to a nonrebreathing mask. Chest. 1991 Dec;100(6):1582-5. PubMed ID: 1959399

Duprez F. Effet du pattern respiratoire sur la FiO2 au cours de l'oxygénothérapie Revue des Maladies Respiratoires. Volume 32, Supplement, January 2015, Page A81

The intervention has been chosen because in our experience, double trunk mask is currently used to fight FDO2 decrease during inspiratory flow increase.

3. STUDY DESIGN

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

The study consisted of two intervention periods separated by a washout period of 20 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 severe hypoxia (See figure 1).

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.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

- *At least 18 years of age*
- *Diagnosed with severe Hypoxia (PaO₂/FiO₂ < 300 mm Hg)*
- *Dyspnea with severe rest at stake accessory muscles of respiration*
- *Respiratory rate (RR) ≥ 25 CPM*
- *PaCO₂ ≤ 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.*

4.2 Exclusion Criteria

- *Hypercapnia (> 45 mm Hg with respiratory acidosis)*
- *Cardiogenic pulmonary edema*
- *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 (CHFONP) classical High Flow Oxygenation with nasal prongs (20 minutes) or CHFNOP with an adjunctive of a DTM.

4.3 Study Enrollment Procedures

Enrolled participants had severe hypoxia being treated at Intensive Care Unit associated with a hospital in Hornu (Epicura).and Tivoli Hospital.

5. STUDY INTERVENTIONS

Interventions, Administration, and Duration

Sequence (Figure 1): The patient should be placed in semi-seated (position at 45 °) Patient will be oxygenated with high-flow nasal cannula (HFNC). Fraction delivered in Oxygen and 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 HFNC.*
- 2. The clinician will associate the Double Trunk Mask (DTM) with the same parameters of the high-flow nasal cannula. Arterial gazometry will be performed after 20 and 60 minutes after placement of DTM.*
- 3. After the withdrawal of DTM, arterial gazometry will be performed after 20 and 60 minutes*

Consenting Procedure

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.

Enrollment, Baseline, and/or Randomization

Enrollment

Enrolled participants had severe hypoxia being treated at Intensive Care Unit associated with a hospital in Hornu (Epicura).and Tivoli Hospital.

Baseline Assessments

For participants who have successfully been screened for eligibility and are enrolled into the study, baseline assessments are performed against which to measure the study outcome:

Age, Weight, Height, arterial pressure (S/D/M), Cardiac frequency, respiratory frequency, PaO₂, PaCO₂, pH, MRC dyspnea, MRC Comfort, Glasgow Coma Scale.

Blinding

Data's should be evaluated in blind by an independent assessor

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.

6. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

Cross over design is the most appropriate to compare one intervention in the same groups of persons

Length of washout chosen is 30 to 60 minutes because after this period, following parameters are stabilized after intervention (PaO₂, PaCO₂, pH)

9.2 Outcomes

Discuss how the outcomes will be analyzed. Describe whether the documentation of an outcome will be reviewed and adjudicated by a committee, how quickly the committee will perform the adjudication, and whether the committee will be masked

to the participant's intervention group assignment.

Primary Outcome

PaO₂ is the primary outcomes observed. PaO₂ is the principal parameters observed

Secondary Outcomes

PaCO₂, pH, MRC dyspnea and comfort

9.3 Data Analyses

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

A sample size of 15 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 were used to compare the difference between participants receiving (high-flow nasal cannula + DTM) and with high-flow 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).

Note: In accordance with NIH policy, if data from prior studies do not negate strongly the existence of significant differences of clinical or public health importance in the intervention effect between gender and racial/ethnic subgroups, a statement should be included noting that a valid analysis of the intervention effect will be performed in these subgroups. If data from prior studies do not strongly support the existence of significant differences in the intervention effect between subgroups, then the analyses need not have high statistical power for detecting clinically meaningful differences.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

For maintaining confidentiality of participant records, all data's will be recorded directly on the CRFs (ICH Guidelines, E6.4.9)