

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of Comfortability and Effectiveness of Total Face Mask and Oronasal Mask in Non-invasive Positive Pressure Ventilation in Patients with Acute Respiratory Failure

Protocol summary

Summary

Study objectives: efficiency and ease of use of two types of face masks or respirators mouth or nose in non-invasive ventilation in patients with acute respiratory failure scholar at Christ's Hospital Study Design: The study is double-blind clinical trial. How the study: First, patients randomly into two groups based on the use of masks or masks for the face, mouth or nose fall. Typically non-invasive ventilation, continuously for 24 hours will apply. In both groups, if the patient received the first mask, not tolerate, before disconnecting non-invasive ventilation mask will be the second try. Conditions of entry and exit from the study: Inclusion criteria included the following: patients with acute respiratory failure; Tachypnea (respiratory rate more than 24); The use of sub-breathing muscles; Paradoxical breathing; Respiratory acidosis Exclusion criteria include: alteration of consciousness; Respiratory hypersecretion; Unstable coronary disease; Arrhythmia leading to unstable blood pressure; Arterial oxygen saturation less than 90% or greater than 40 mm Hg drop from Fsharqbly; Large skin lesion; Trauma to the face; Upper airway obstruction; Recent surgery on the upper airway, stomach and esophagus; A situation that requires immediate intubation. The main outcome variables: the convenience of using a mask with a score of 0 to 10. Secondary outcome variables: venous blood gas profile

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051627929N1**
Registration date: **2016-06-15, 1395/03/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-15, 1395/03/26

Registrant information

Name

Atefeh Fakharian

Name of organization / entity

National research institute of tuberculosis and lung diseases

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

From the budget of thesis

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Comfortability and Effectiveness of Total Face Mask and Oronasal Mask in Non-invasive Positive Pressure Ventilation in Patients with Acute Respiratory Failure

Public title

Comfortability and Effectiveness of Non-invasive Positive Pressure Ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included the following: patients with acute respiratory failure; Tachypnea (respiratory rate more than 24); The use of sub-breathing muscles; Paradoxical breathing; Respiratory acidosis Exclusion criteria include: alteration of consciousness; Respiratory hypersecretion; Unstable coronary disease; Arrhythmia leading to unstable blood pressure; Arterial oxygen saturation less than 90% or greater than 40 mm Hg drop from Fsharqibly; Large skin lesion; Trauma to the face; Upper airway obstruction; Recent surgery on the upper airway, stomach and esophagus; A situation that requires immediate intubation.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin

City

Tehran

Postal code

Approval date

2014-07-02, 1393/04/11

Ethics committee reference number

sbmu1.REC.1393.65

Health conditions studied

1

Description of health condition studied

respiratory failure

ICD-10 code

J96.0

ICD-10 code description

Acute respiratory failure

Primary outcomes

1

Description

comfortability of mask

Timepoint

daily

Method of measurement

visual analog scale (VAS) questionnaire

Secondary outcomes

1

Description

Venous PH

Timepoint

Daily

Method of measurement

venous blood gass

2

Description

Venous PCO2

Timepoint

Daily

Method of measurement

venous blood gass

3

Description

Venous HCO3-

Timepoint

Daily

Method of measurement

venous blood gass

Intervention groups

1

Description

In the intervention group: the mouth or nose mask is used. Non-invasive device configurations based on guidelines published by the Lung Association will be conducted in Europe and America. The mask is placed on the patient for 24 hours. If the patient's mouth mask used to mask other group used In the second group of

face mask is used. Non-invasive device settings in this group are similar to the first group and based on guidelines published by the Lung Association is done in Europe and America.

Category

Treatment - Devices

2**Description**

In control group, Full face masks used in the control group. Non-invasive device settings in this group are similar groups on the basis of guidelines published by the Lung Association is done in Europe and America. The mask is placed on the patient for 24 hours. If the patient fails to mask another mask for used

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Atefeh Fakharian

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahid Beheshti university of medical sciences

Full name of responsible person

Dr. Afshin Rezghi

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7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Atefeh Fakharian

Position

Pulmonologist

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Web page address**Person responsible for updating data****Contact**

Name of organization / entity

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty