Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Efficacy of High-Flow Nasal Oxygen Therapy and Noninvasive Ventilation in patients with COPD Exacerbation

Protocol summary

Study aim
The efficacy of treatment of exacerbated chronic pulmonary patients with the treatment of high flow of oxygen therapy compared with receiving non-invasive ventilation

Design
Clinical trial, randomized, two parallel intervention groups, double-blind. Sample size 68

Settings and conduct
Patients' recovery with two methods of high-flow Nasal Oxygen Therapy and Noninvasive Ventilation by examining ABG parameters will be compared and analyzed (effectiveness of these two methods). Randomization will be done according to computer generated random numbers. The studied population is part of the target population (all people with exacerbated COPD) who come to Dr. Masih Daneshvari hospital.

Participants/Inclusion and exclusion criteria
The presence of chronic obstructive pulmonary disease (COPD) and acute respiratory failure; 7.25 < pH < 7.35; Arterial pressure of carbon dioxide (PaCO2) equal to or greater than 45 mmHg.

Intervention groups
People with exacerbated chronic pulmonary disease are divided into two groups. In one group, the effectiveness of NIV and in the other group the effectiveness of HFNT are examined and compared.

Main outcome variables
ABG

General information

Reason for update
The recruitment start date was changed and the trial was started from July 2019.

Acronym

IRCT registration information
IRCT registration number: **IRCT20160516027929N7**
Registration date: **2020-01-25, 1398/11/05**
Registration timing: **retrospective**

Last update: **2020-05-31, 1399/03/11**
Update count: **1**

Registration date
2020-01-25, 1398/11/05

Registrant information

Name
Atefeh Fakharian

Name of organization / entity
National research institute of tuberculosis and lung diseases

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Efficacy of High-Flow Nasal Oxygen Therapy and Noninvasive Ventilation in patients with COPD Exacerbation

Public title

Comparison of the Efficacy of High-Flow Nasal Oxygen Therapy and Noninvasive Ventilation in patients with COPD Exacerbation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of chronic obstructive pulmonary disease (COPD) and acute respiratory failure pH < 7.35 Arterial pressure of carbon dioxide (PaCO2) equal to or greater than 45mmHg

Exclusion criteria:

- Mechanical ventilation in the past 60 days (using any non-invasive ventilation or high blood oxygen through the nasal cannula (HFNT) prior to enrollment in the study and after the onset of acute upper respiratory failure (AHRF) - Non-invasive ventilation for home care - Undesirable clinical condition (require a vasopressor for> 24 hours, acute coronary syndrome or life-threatening arrhythmias (- Refusal of treatment - Disorder in more than two organs -Heart failure - The respiratory tract requires a tracheal intubation - Trauma or burn in the neck and face - Pregnancy - Refusal of consent - enter to other research protocols

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple Unit of randomization : individual Tools used in randomization : table of random numbers Included patients, in a simple randomized evaluation using even and odd numbers, would got codes for each treatment group. In case of odd numbers, the patient would be enrolled in the group one to receive high flow oxygenation at the first stage and following a washout period, take noninvasive ventilation. On the other hand, patients gotten even numbers would receive noninvasive ventilation for the first stage. Then, after a washout period, high oxygen therapy would be prescribed.

Blinding (investigator's opinion)

Double blinded

Blinding description

To treat any possible complications, the care provider is not blind. Other blind groups are as below: Participants, investigators, outcome assessor, Data analyse.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti of Medical Sciences

Street address

Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran

City

Tehran

Province

Tehran

Postal code

19556

Approval date

2019-06-01, 1398/03/11

Ethics committee reference number

IR.SBMU.NRITLD.REC.1398.032

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease (COPD)

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description

PaCO2

Timepoint

before intervention- one hour after - half hour after- after intervention

Method of measurement

ABG

Secondary outcomes

1

Description

SaO2

Timepoint

befor intervention-one hour after-half hour after- after intervention

Method of measurement

ABG

Intervention groups

1

Description

Intervention group: Intervention group: First, ABG will be measured and then HFNT will be performed and after 1 hour, ABG will be measured again. Then 30 minutes will be passed without the device, after which ABG will be measured again. Eventually 1 hour NIV will be performed and ABG will be measured with the VPAP device.

Category

Treatment - Devices

2

Description

Intervention group 2: First ABG will be measured and then the NIV will be performed, after 1 hour, ABG will be measured by the VPAP. Next 30 minutes will be without device and then ABG will be measured again. Then 1 hour HFNT will be done and ABG will be evaluated at the end.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran

Full name of responsible person

Atefeh Fakharian

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Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefeh Fakharian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Poulmonologist

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available