Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of using high flow oxygen delivery through nasal cannula (HFNC) with different currents, in improving the respiratory symptoms of patients with chronic obstructive pulmonary disease (COPD) referred to Masih Daneshvari Hospital

Protocol summary

Study aim
Evaluation of oxygen therapy through HFNC with different currents, in improving the respiratory symptoms of patients with COPD in Masih Daneshvari Hospital.

Design
The present study is a clinical trial with three intervention groups, with parallel and one-way blind groups, randomized and with a sample size of 30 patients.

Settings and conduct
This study is performed as a clinical trial in patients with COPD referred to Masih Daneshvari Hospital in Tehran who need to be hospitalized and receive respiratory support. The collected data are real and experimental. Based on the objectives and hypotheses of this study, the clinical conditions and parameters obtained from the analysis of blood gases and spirometry of patients after receiving high-current conductive oxygen through the nasal cannula will be examined. Randomization is done using codes assigned to each patient and based on the file number. For the treatment of any possible complication, the main therapist has knowledge of the groups. Other groups kept blind include the researcher analyzing the data.

Participants/Inclusion and exclusion criteria
Signing a written consent form, no intubation, hypoxemic respiratory distress

Intervention groups
Patients are divided into 3 groups according to the opinion of the therapist with different flows of 30, 40, and 60 liters per minute. The air will be transferred to the patient through the nasal cannula and the patient will be taught how to breathe properly before starting oxygen therapy. Except for FiO2, the other settings of the high flow device are set equally for all three groups, and the air temperature is set at 34 ° C to ensure proper humidity to the patient's inhaled air.

Main outcome variables
Arterial blood gas analysis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160516027929N9**
Registration date: **2021-03-19, 1399/12/29**
Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**
Update count: **0**

Registration date
2021-03-19, 1399/12/29

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

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of using high flow oxygen delivery through nasal cannula (HFNC) with different currents, in improving the respiratory symptoms of patients with chronic obstructive pulmonary disease (COPD) referred to Masih Daneshvari Hospital

Public title

Evaluation of the effect of HFNC use in COPD patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signing a written consent form No intubation Hypoxemic respiratory distress

Exclusion criteria:

PaCO2> 65 pH < 7.28 Age less than 18 years Cardiovascular disorders that prevent respiratory rehabilitation Diagnosis of medical staff based on the patient's absence from participating in this study

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization. Randomization unit: individual. Randomization tool: Random number table. Patients are divided into 3 groups treated with different flows of 30, 40, and 60 liters per minute based on the codes assigned to each patient (using file number).

Blinding (investigator's opinion)

Single blinded

Blinding description

To prevent any possible complications, the primary caregiver is aware of the allocation of treatment groups. Patients in the study were also not blinded to the treatment they were receiving. Researchers responsible for data collection and analysis are not aware of the allocation of different study groups

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

Dr. Masih Daneshvari Hospital, Darabad, Shahid Bahonar St. (Niavaran)

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.220

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44

ICD-10 code description

chronic obstructive pulmonary disease

Primary outcomes

1

Description

Forced expiratory volume in first second

Timepoint

Before starting oxygen therapy, 24 hours later

Method of measurement

Spirometry

2

Description

Oxygen saturation

Timepoint

Before starting oxygen therapy, 24 hours later

Method of measurement

Pulse oximetry

3

Description
Forced vital capacity
Timepoint
Before starting oxygen therapy, 24 hours later
Method of measurement
Spirometry

4

Description
Partial pressure of carbon dioxide
Timepoint
Before starting oxygen therapy, 24 hours later
Method of measurement
VBG analysis

Secondary outcomes

1

Description
Borg scale
Timepoint
Before starting oxygen therapy, 24 hours later
Method of measurement
Questionnaire review

2

Description
CAT score
Timepoint
Before starting oxygen therapy, 24 hours later
Method of measurement
Questionnaire review

Intervention groups

1

Description
First intervention group: In this group, patients receive oxygen therapy through a high-flow device. The patient's transport oxygen flow is set to 30. The inlet air temperature is set to 34 ° C to ensure proper humidity to the patient's inhaled air.
Category
Treatment - Devices

2

Description
Second intervention group: In this group, patients receive oxygen therapy through a high-flow device. The patient's transport oxygen flow is set to 40. The inlet air temperature is set to 34 ° C to ensure proper humidity to the patient's inhaled air.
Category
Treatment - Devices

3

Description
Third intervention group: In this group, patients receive oxygen therapy through a high-flow device. The patient's transport oxygen flow is set to 60. The inlet air temperature is set to 34 ° C to ensure proper humidity to the patient's inhaled air.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Mahrokh Fargah
Street address
Masih Daneshvari Hospital, Darabad
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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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Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran Highway
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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
Associate professor
Latest degree
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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
There is 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
Undecided - It is not yet known if there will be 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