# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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
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Masih Daneshvari Hospital, Darabad
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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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
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**Position**
Associate professor
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## Person responsible for updating data

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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