

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

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

#### Protocol summary

Registration timing: **retrospective**

#### 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

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

Update count: **1**

#### Registration date

2020-01-25, 1398/11/05

#### Design

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

#### Registrant information

##### Name

Atefeh Fakharian

##### Name of organization / entity

National research institute of tuberculosis and lung diseases

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2712 2541

##### Email address

afakharian@sbmu.ac.ir

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

The presence of chronic obstructive pulmonary disease (COPD) and acute respiratory failure;  $7.25 < \text{pH} < 7.35$ ; Arterial pressure of carbon dioxide ( $\text{PaCO}_2$ ) equal to or greater than 45 mmHg.

#### 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

#### 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.

#### Scientific title

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

#### Main outcome variables

ABG

#### Public title

#### 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**

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 (PaCO<sub>2</sub>) 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 get 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**

PaCO<sub>2</sub>

#### **Timepoint**

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

#### **Method of measurement**

ABG

### **Secondary outcomes**

#### 1

#### **Description**

SaO<sub>2</sub>

#### **Timepoint**

before 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

**Street address**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Atefeh Fakharian

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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**

Pulmonologist

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

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## Person responsible for updating data

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**Position**

Assistant professor

**Latest degree**

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**Web page address**

## 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