

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the effect of Non-Invasive Ventilation (NIV) and Venturi mask on Impulse Oscillometry (IOS) parameters in hospitalized patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)

#### Protocol summary

##### Study aim

Comparison of the effect of non-invasive ventilation (NIV) and Venturi mask on impulse oscillometry (IOS) parameters in hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease (COPD)

##### Design

A phase 3, randomized, double-blind, parallel-group, clinical trial conducted on 60 patients. Permuted block randomization will be used for randomization.

##### Settings and conduct

This study is conducted as a clinical trial (double-blind) on hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease visiting Masih Daneshvari Hospital in Tehran. In the NIV group, patients receive non-invasive ventilation with an appropriate mask, and in the Venturi group, they receive oxygen through a Venturi mask.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for the study include increased shortness of breath, increased sputum volume or purulence, and oxygen saturation below 88%, arterial blood gas with pH greater than or equal to 7.30 and PaCO<sub>2</sub> greater than or equal to 45 mmHg, and the ability to perform the IOS test. Exclusion criteria include severe acidosis, respiratory arrest or immediate need for intubation, severe hemodynamic instability, need for invasive ventilation, presence of lobar consolidation, active pneumothorax, and very high BMI.

##### Intervention groups

In the NIV group, patients were placed on non-invasive ventilation with an appropriate mask and positive airway pressure during inspiration (IPAP) of 10–14 cm H<sub>2</sub>O, positive airway pressure during expiration of 4–6 cm H<sub>2</sub>O, and the fraction of inspired oxygen was adjusted to a range of 88–92%. In the Venturi group, patients were

placed on a Venturi mask with blood oxygen saturation (O<sub>2</sub>sat) maintained at 88 to 92%.

##### Main outcome variables

Total airway resistance, central airway resistance, reactivity at 5 Hertz, resonance frequency, reactance area

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160516027929N13**

Registration date: **2026-05-31, 1405/03/10**

Registration timing: **prospective**

Last update: **2026-05-31, 1405/03/10**

Update count: **0**

##### Registration date

2026-05-31, 1405/03/10

##### Registrant information

##### Name

Atefeh Fakharian

##### Name of organization / entity

National research institute of tuberculosis and lung diseases

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

afakharian@sbmu.ac.ir

##### Recruitment status

**Not yet recruiting**

##### Funding source

**Expected recruitment start date**

2026-07-23, 1405/05/01

**Expected recruitment end date**

2027-01-21, 1405/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of Non-Invasive Ventilation (NIV) and Venturi mask on Impulse Oscillometry (IOS) parameters in hospitalized patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD)

**Public title**

Comparison of the effectiveness of non-invasive ventilation and Venturi mask in patients with chronic obstructive pulmonary disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease (COPD) Dyspnea Oxygen saturation (SpO<sub>2</sub>) less than 88% on room air pH greater than or equal to 7.30 Partial pressure of carbon dioxide (PaCO<sub>2</sub>) greater than or equal to 45 mmHg in arterial blood gases (ABG) upon admission Appropriate level of consciousness (Glasgow Coma Scale 15) Ability to cooperate and perform Impulse Oscillometry test Informed consent to participate in the study

**Exclusion criteria:**

Patient's unwillingness to participate in the research study

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method used is permuted block randomization. For this purpose, two treatment groups, A and B, are defined in blocks as AB and BA. Then, numbers from a random table in the range 0 to 9 are considered. Numbers 0 to 4 are assigned to block AB, and numbers 5 to 9 are assigned to block BA. Random numbers are then selected from the table. If the number 0 appears, it corresponds to block AB, and therefore two individuals enter this block, such that the first individual receives

treatment A and the second individual receives treatment B. In the same way, the treatment groups for the remaining participants are determined. Although in this method the number of observations in both groups will be equal, because of the small block sizes, there is a high probability that the person conducting the study may predict the treatment group assignment. To solve this problem, the randomization list is prepared before the start of the study by a blinded individual who is not part of the treatment team. Additionally, the block sizes will be increased.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To ensure blinding, patients are placed in separate rooms and are unaware of their group assignment. Additionally, the operator responsible for performing Impulse Oscillometry is different from the nurse who sets up the non-invasive ventilation or Venturi mask for the patient. This operator is blinded to the patient grouping during the Impulse Oscillometry test, which is conducted in a location separate from the intervention site. Furthermore, the data analyst will only have access to coded data (Group A and Group B) and will remain blinded to the nature of the groups until the end of the statistical analysis process.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of School of Medicine, Shahid Beheshti University of Medical Sciences

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Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Approval date**

2026-05-05, 1405/02/15

**Ethics committee reference number**

IR.SBMU.MSP.REC.1405.061

**Health conditions studied**

## 1

### **Description of health condition studied**

Chronic obstructive pulmonary disease

### **ICD-10 code**

J44.1

### **ICD-10 code description**

Chronic obstructive pulmonary disease with (acute) exacerbation

## **Primary outcomes**

### 1

#### **Description**

Airway resistance at 5 Hz frequency (R5)

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Impulse Oscillometry

### 2

#### **Description**

Airway resistance at 20 Hz frequency (R5)

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Impulse Oscillometry

### 3

#### **Description**

Resistance heterogeneity level (R5-R20)

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Impulse Oscillometry

### 4

#### **Description**

Input Impedance (X5)

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Impulse Oscillometry

### 5

#### **Description**

Resonance frequency (Fres)

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Impulse Oscillometry

## 6

### **Description**

Resonance area (AX)

### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

### **Method of measurement**

Impulse Oscillometry

## **Secondary outcomes**

### 1

#### **Description**

Oxygen saturation percentage

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Pulse oximetry

### 2

#### **Description**

Peripheral blood eosinophil

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Counting of blood cells

### 3

#### **Description**

Number of disease exacerbations

#### **Timepoint**

From the beginning of entering the study to the end of the study

#### **Method of measurement**

Self-expression

### 4

#### **Description**

Blood acidity (pH)

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Venous Blood Gas Analysis

### 5

#### **Description**

Bicarbonate

#### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

#### **Method of measurement**

Venous Blood Gas Analysis

## 6

### **Description**

Partial pressure of carbon dioxide

### **Timepoint**

Before the intervention (the first day of hospitalization) and after the intervention (on the fourth day)

### **Method of measurement**

Venous Blood Gas Analysis

## **Intervention groups**

### 1

#### **Description**

Intervention group: In the NIV group, patients are placed on non-invasive ventilation with an appropriate mask. The initial device settings will be standard as follows: IPAP: 10-14 cmH<sub>2</sub>O EPAP: 4-6 cmH<sub>2</sub>O FiO<sub>2</sub> adjustment with the goal of maintaining oxygen saturation (SpO<sub>2</sub>) in the range of 88-92% Settings can be adjusted based on patient tolerance, reduction of dyspnea, and improvement of respiratory indices.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: In the Venturi group, patients receive the required oxygen with the following settings: the percentage of the Venturi mask will be determined to maintain O<sub>2</sub> saturation at 88 to 92.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Masih Daneshvari Hospital

##### **Full name of responsible person**

Atena Nayebi

##### **Street address**

Darabad, Masih Daneshvari Hospital

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin Zarghi

##### **Street address**

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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**

Mohsen Sadeghi

##### **Position**

Assistant professor

##### **Latest degree**

Subspecialist

##### **Other areas of specialty/work**

Internal Medicine

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## Person responsible for scientific inquiries

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Hamidreza Jamaati

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Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available