

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effectiveness of High-Flow Oxygen Therapy on clinical and spirometry findings in Acute Exacerbation of Asthma

#### Protocol summary

##### Summary

**Objectives:** This study compared high flow oxygen therapy and oxygen at low flow in patients with acute asthma attack admitted in the emergency department.

**Design:** A prospective double-blind trial pilot study was designed

**Method:** patients randomly assigned to groups, high flow oxygen therapy and low flow oxygen therapy. Both groups receive other treatments for asthma attack.

**Outcome variables before, 2 hours and 24 hours after interventions are evaluated.** Participants, the main entry and exit conditions: All patients admitted to the emergency department of Masih daneshvari hospital with acute asthmatic attack in a period of twelve months, that fulfill the acceptance criteria have been enrolled.

**Inclusion criteria:** history of asthma; aged between 18 and 65 years; Non-smoking; not pregnant; Lack of occupational asthma

**Exclusion criteria:** critically ill patients requiring intensive care unit (life-threatening asthma); Infiltrates on chest x-ray; Hypercapnic respiratory failure

**Interventions:** In addition to standard medical treatment, the control group received less than 10 liters per minute flow rate of oxygen. The intervention group also received standard medical treatment in addition to high flow oxygen dampened with over 10 liters per minute.

**Outcome variables:** the Borg dyspnea score; Vital signs including respiratory rate; heart rate; blood pressure; temperatures; Spirometry; Peak flow meter; blood gases; blood cell counts; immunoglobulin E; Interleukin

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081727929N2**  
Registration date: **2016-09-10, 1395/06/20**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-10, 1395/06/20

##### 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

##### Recruitment status

**Recruitment complete**

##### Funding source

From research found

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of High-Flow Oxygen Therapy on clinical and spirometry findings in Acute Exacerbation of Asthma

##### Public title

Effectiveness of High-Flow Oxygen Therapy on clinical and spirometry findings in Acute Exacerbation of Asthma

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Admission criteria: a history of asthma; aged between 18 and 65 years; no history of smoking; no pregnancy; no history of occupational asthma Exclusion criteria: critically ill patients requiring intensive care unit (life-threatening asthma); infiltrates on chest x-ray ; Hypercapnic respiratory failure

### **Age**

From **18 years** old to **65 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size:

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **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**

7th Floor, Bldg No.2 shahid beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2016-08-09, 1395/05/19

#### **Ethics committee reference number**

IR.SBMU.NRITLD.REC.1395.230

## **Health conditions studied**

### 1

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

Acute asthma

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

J46

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

Acute severe Asthma

## **Primary outcomes**

### 1

#### **Description**

Respiratory rate

#### **Timepoint**

before, 2 and 24 hours after intervention

#### **Method of measurement**

Examination

### 2

#### **Description**

Dyspnea score

#### **Timepoint**

before, 2 and 24 hours after intervention

#### **Method of measurement**

Borg scale

### 3

#### **Description**

arterial oxygen saturation

#### **Timepoint**

before, 2 and 24 hours after intervention

#### **Method of measurement**

Arterial blood gas analysis

## **Secondary outcomes**

### 1

#### **Description**

peak expiratory flow

#### **Timepoint**

before, 2 and 24 hours after intervention

#### **Method of measurement**

peak flowmeter

### 2

#### **Description**

forced expiratory volume in 1st second

#### **Timepoint**

before, 2 and 24 hours after intervention

#### **Method of measurement**

spirometry

## **Intervention groups**

### 1

#### **Description**

Control group: oxygen therapy with low flow (less than 10 liters per minute)

#### **Category**

Treatment - Devices

## 2

### Description

The intervention group received high-flow oxygen (between 10 to 50 liters per minute)

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

National research institute of tuberculosis and lung diseases

##### Full name of responsible person

Atefeh Fakharian

##### Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-Chancellor in Research Affairs shahid Beheshti university of medical sciences

##### Full name of responsible person

Afshin Rezghi

##### Street address

7th Floor, Bldg No.2 shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice-Chancellor in Research Affairs shahid Beheshti university of medical sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

National research institute of tuberculosis and lung diseases

#### Full name of responsible person

Sharareh Raeisi

#### Position

pulmonary medicine fellowship

#### Other areas of specialty/work

#### Street address

Masih Daneshvari Hospital, Darabad

#### City

Tehran

#### Postal code

#### Phone

+98 21 2712 2000

#### Fax

#### Email

shraeisi86@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

National research Institute of Tuberculosis and lung diseases

#### Full name of responsible person

Atefeh Fakharian

#### Position

pulmonologist

#### Other areas of specialty/work

#### Street address

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fakharian\_2005@yahoo.com

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## Person responsible for updating data

### Contact

#### Name of organization / entity

National research institute of tuberculosis and lung diseases

#### Full name of responsible person

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pulmonologist

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*