

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma

#### Protocol summary

##### Study aim

The effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma

##### Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

##### Settings and conduct

the current clinical trial study will be conducted on patients with acute Asthma who referred to the Emergency Department of a hospital. On arrival Peak expiratory flow(PEF) of all individuals will be measured. Patients will be classified into two groups with a different type of medicine. they will take medicine several times. After receiving each dose, the PEF will be measured. Finally, the average of PEF and the duration of admission will be compared between two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Patients with Acute Asthma ,Definitive diagnosis of asthma ,being older than 18 Exclusion criteria the Flu ,Patients who are treated with other forms of medication ,Pregnant patients ,obvious infection in Chest X-ray ,Patient with heart, kidney, liver disease

##### Intervention groups

receiving Below items through nebulizer: Control group: Oxygen, spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone + distilled water intervention group: Oxygen, spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone + budesonide

##### Main outcome variables

PEF hospitalization duration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170531034256N2**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

##### Registration date

2019-05-27, 1398/03/06

##### Registrant information

###### Name

Atefeh Abedini

###### Name of organization / entity

Chronic Respiratory Diseases Research Center,  
National Research Institute of Tuberculosis and Lung  
D

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2712 2031

###### Email address

dr.abedini110@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma

**Public title**

Effectiveness of the Treatment With Budesonide Nebuliser among Patients with Acute Asthma

**Purpose**

Treatment

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

Definitive diagnosis of asthma being older than 18

**Exclusion criteria:**

the Flu Patients who are treated with other forms of medication Pregnant patients obvious infection in Chest X-ray Patient with heart , kidney, liver disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals are randomly assigned to one of two study groups with the help of a random number table and receive the intervention of the same group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

\*A statistician will classify the patients based on the random numbers in either group one (control group) or group 2 (intervention group). This person is unaware of the type of treatment which they will receive in each group. \* Patients will be informed about two potential types of treatment but they won't know they will receive which of those. \* The nurse will give the patients' unlabeled medicine based on their code.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Shahid B

**Street address**

Masih Daneshvari Hospital, DAR ABAD

**City**

Tehran

**Province**

Tehran

**Postal code**

19569-44413

**Approval date**

2019-02-04, 1397/11/15

**Ethics committee reference number**

IR.SBMU.NRITLD.REC.1397.064

**Health conditions studied****1****Description of health condition studied**

Asthma

**ICD-10 code**

J45.21

**ICD-10 code description**

Mild intermittent asthma with (acute) exacerbation

**Primary outcomes****1****Description**

Peak expiratory flow

**Timepoint**

0 min, 30 min, 60 min, 90 min

**Method of measurement**

Peak Flow Meter

**2****Description**

hospitalization duration

**Timepoint**

final

**Method of measurement**

questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: On arrival, PEF of all individuals will be evaluated. The so-called intervention group will receive Oxygen, the spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone based on Gina guideline in addition to budesonide (at the arrival, 0.5-ml budesonide will be taken and this will be repeated every 30 minutes for three times) using a nebulizer.

**Category**

Treatment - Drugs

## 2

### Description

Control group: On arrival, PEF of all individuals will be evaluated. The so-called control group will receive Oxygen, the spray containing Salbutamol and Ipratropium bromide, corticosteroids in the form of hydrocortisone based on Gina guideline in addition to distilled water (at the arrival, 0.5-ml distilled water will be taken and this will be repeated every 30 minutes for three times) using a nebulizer.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

the Emergency Department of Masih Daneshvari Hospital

##### Full name of responsible person

Atefeh Abedini

##### Street address

Masih Daneshvari hospital, Dar Abad

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

+98 21 2712 2031

##### Email

dr.abedini110@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Masih Daneshvari hospital, Dar Abad

##### City

Tehran

##### Province

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##### Postal code

19569-44413

##### Phone

+98 21 8820 0096

##### Email

zarghi@sbmu.ac.ir

##### 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

Fatemeh Razavi

##### Position

Researcher

##### Latest degree

Master

##### Other areas of specialty/work

Pulmonology

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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout,

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##### Email

Fatemehrazavi@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Arda Kiani

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

pulmonology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Atefeh Abedini  
**Position**  
assistance professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
pulmonology  
**Street address**  
Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout,  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**

## 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