

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of the effect of inhaled corticosteroid in the prevention of thunderstorm asthma

#### Protocol summary

##### Summary

The goal of the study is to prevent asthma thunderstorm. Clinical trials are randomized, control group with placebo and double blind. Inclusion criteria includes persons with the history of TS asthma. Exclusion criteria includes the persons with higher than 60 years and lower than 14 years old; use asthma maintenance drugs at the beginning of study; having asthma symptoms at the beginning of study; having chronic asthma at the start of study; FEV1 less than predicted eighty percent; appearing the asthma symptoms during the study so that patient needs maintenance treatment; symptoms of acute coronary syndrome; pregnant women; disability to do spirometry with high quality; Contraindications to perform spirometry; asking patients to get out of the study. Sample size is 54 persons. This study has intervention with inhaled budesonide. The date of intervention is three months. The primary outcome is to measure FEV1 whose time point measurement is three months after starting intervention and the method of measurement is spirometry. Secondary outcome is to study of asthma exacerbation whose time point measurement is three months after starting intervention and method of measurement is questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102520828N2**  
Registration date: **2017-01-02, 1395/10/13**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-02, 1395/10/13

#### Registrant information

##### Name

Maryam Haddadzadeh Shoushtari

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3292 1839

##### Email address

haddadzadeh-m@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Deputy for Research of Ahvaz Jundishapur University of Medical Sciences

#### Expected recruitment start date

2016-10-06, 1395/07/15

#### Expected recruitment end date

2017-01-04, 1395/10/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the effect of inhaled corticosteroid in the prevention of thunderstorm asthma

#### Public title

Prevention of thunderstorm asthma

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria includes persons with the history of TS asthma. Exclusion criteria includes the persons with higher than 60 years and lower than 14 years old; use asthma maintenance drugs at the beginning of study;

having asthma symptoms at the beginning of study; having chronic asthma at the start of study; FEV1 less than predicted eighty percent; appearing the asthma symptoms during the study so that patient needs maintenance treatment; symptoms of acute coronary syndrome; pregnant women; disability to do spirometry with high quality; Contraindications to perform spirometry; asking patients to get out of the study.

**Age**

From **14 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ahvaz Jundishpur University of Medical Sciences

**Street address**

Golestan

**City**

Ahvaz

**Postal code**

61357-15794

**Approval date**

2016-11-05, 1395/08/15

**Ethics committee reference number**

IR.AJUMS.REC.1395.477

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

Thunderstorm asthma

**ICD-10 code**

J45

**ICD-10 code description**

Asthma

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

FEV1

**Timepoint**

After three months

**Method of measurement**

spirometry

**Secondary outcomes****1****Description**

Asthma exacerbation measurement

**Timepoint**

After three months

**Method of measurement**

Fill in standard asthma exacerbation questionnaire

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

inhaled budesonide, 400 microgram daily for three months

**Category**

Treatment - Drugs

**2****Description**

inhaled placebo,400 microgram daily for three months

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ahvaz Imam Khomeini Hospital

**Full name of responsible person**

Saberh Shahhaidari

**Street address**

Ahvaz Imam khomeini Hospital

**City**

Ahvaz

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Behzad Sharif Makhmalzadeh

**Street address**

Golestan

**City**

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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**

Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Sabere Shaheideari

**Position**

Internal resident

**Other areas of specialty/work**

**Street address**

Imam Khomeini hospital- Internal Medicine-  
Pulmonary ward

**City**

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6193673166

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+98 61 3221 5574

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sabere.sabor@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Maryam Haddadzadeh Shoushtari

**Position**

pulmonology subspecialist

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

**Contact**

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Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Farzaneh Hayati

**Position**

Research master

**Other areas of specialty/work**

**Street address**

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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*