

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

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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

Ahvaz

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

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Person responsible for scientific inquiries

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Position

pulmonology subspecialist

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Farzaneh Hayati

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Web page address

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