

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Tacrolimus on improving clinical symptoms, FEV1 and PEFR in patients with acute asthma attack ; Randomized clinical trial

Protocol summary

Summary

The aim of this study is the evaluation of effects of Tacrolimus on improving clinical symptoms, FEV1 and PEFR in patients with acute asthma attack. This double blind randomized clinical trial will be carried out on 70 patients with severe asthma, who are referred to emergency department due to an asthma attack. The intervention group will be received 0.5 mg ipratropium nubilized (repeated up to 3 doses in every 20 minutes), 5 mg Albuterol inhalation and Prednisolon at the beginning (zero time point). Also, 2 mg nebulized Tacrolimus (2 mg Tacrolimus, diluted in 2 cc of normal saline). The control group will be received 0.5 mg nubilized ipratropium (repeated up to 3 doses in every 20 minutes), 5 mg Albuterol inhalation and Prednisolon at the beginning (zero time point), similar to experimental group, as well as taking 2 cc nubilized normal saline as placebo in the beginning. Pulmonary function (FEV1 and PEFR), hemodynamic variables (blood pressure, pulse and respiration rate, pressure of oxygen in arterial blood) will be compared at the time points of 0, 30, 60, 90 and 120 after the intervention for all the studied patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017063015446N11**

Registration date: **2017-07-25, 1396/05/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

Hassan Motamed

Name of organization / entity

Emergency Department , Ahvaz Jundishapour
University of Medical Sciences , Ahvaz , Iran

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

motamed-h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences, Ahvaz,
Iran

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Tacrolimus on improving clinical symptoms,
FEV1 and PEFR in patients with acute asthma attack ;
Randomized clinical trial

Public title

Tacrolimus in improving clinical symptoms patients with
acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age between 18 and 65 years;
patients with shortness of breath; cases with a history of

asthma that correlate with their clinical and paraclinical parameters Exclusion criteria: The patients with tacrolimus allergy; HCO-60 (polyoxyl 60 hydrogenated castor oil); Hyperpigmentation scars, diabetes mellitus; renal failure; heart failure; electrolyte disorders; uncontrolled blood pressure; neurologic disorders; lymphoma and other malignancies; pregnancy and breast feeding

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization was done by block randomization method

Secondary Ids

empty

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

The ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blv

City

Ahvaz

Postal code**Approval date**

2017-02-28, 1395/12/10

Ethics committee reference number

IR.AJUMS.REC.1395.768

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

asthma

ICD-10 code

J45

ICD-10 code description

Asthma

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

PEFR

Timepoint

0,30,60,120 and 150 minutes after treatment

Method of measurement

spirometry

2**Description**

FEV1

Timepoint

0,30,60,120 and 150 minutes after treatment

Method of measurement

spirometry

Secondary outcomes

empty

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

The intervention group will receive 0.5 mg ipratropium nebulized (repeated up to 3 doses in every 20 minutes) , 5 mg Albuterol inhalation and Prednisolon at the beginning (zero time point). Also, 2 mg nebulized Tacrolimus (2 mg Tacrolimus diluted in 2 cc of normal saline).

Category

Treatment - Drugs

2**Description**

The control group will receive 0.5 mg nebulized ipratropium (repeated up to 3 doses in every 20 minutes) , 5 mg Albuterol inhalation and Prednisolon at the beginning (zero time point).

Category

Treatment - Drugs

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

Golestan Hospital

Full name of responsible person

Hassan Motamed

Street address**City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hasan Motamed

Street address

Farvardin Blv

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

Hasan Motamed

Position

M.D

Other areas of specialty/work

Street address

Farvardin Blv

City

Ahvaz

Postal code

Phone

+98 61 3374 3009

Fax

Email

mtdhsn@gmail.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

Hasan Motamed

Position

M.D

Other areas of specialty/work

Street address

Farvardin Blv

City

Ahvaz

Postal code

Phone

+98 61 3374 3009

Fax

Email

mtdhsn@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hasan Motamed

Position

M.D

Other areas of specialty/work

Street address

Farvardin Blv

City

Ahvaz

Postal code

Phone

+98 61 3374 3009

Fax

Email

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