# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 nubulized (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 nubulized 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 nubulized 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**

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

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

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**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 nubulized (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**

Ahvaz

## 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**
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## Person responsible for updating data

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**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*