

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of montelukast efficacy on clinical and FEV1/PEFR improvement in acute asthma attack

Protocol summary

Summary

Goal: analysis of oral Montelukast in acute asthma exacerbation. This clinical trial study will be done on 80 patients in case and control groups, we'll give Montelukast in addition to standard treatment to the case group and so the control group will receive standard treatment and results will be analyzed between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092215446N5**
Registration date: **2015-12-27, 1394/10/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-27, 1394/10/06

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

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-06-27, 1394/04/06

Expected recruitment end date

2017-01-21, 1395/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of montelukast efficacy on clinical and
FEV1/PEFR improvement in acute asthma attack

Public title

Evaluation of montelukast efficacy on clinical and
FEV1/PEFR improvement in acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age above 18 years old; documented
asthmatic patients with spirometry. Exclusion criteria:
no response to therapy; use of epinephrine or MgSO4 or
IPPV during treatment; patient refuse from continue of
treatment; lung diseases like ILD; cigarette smoking.

Age

From **18 years** old

Gender

Both

Phase

3

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Research Assistant, Next to central Building, Ahvaz Jundishapur University of Medical Sciences, University town, Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2015-06-27, 1394/04/06

Ethics committee reference number

IR.AJUMS.REC.1394.228

Health conditions studied

1

Description of health condition studied

Acute attack asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Clinical state

Timepoint

Before intervention, 30, 60, 90, 150 minutes after intervention

Method of measurement

Base on alert status, talking, wizing, use of respiratory mu

2

Description

Forced Expiratory Volum in First Secend (FEV1)

Timepoint

Before intervention, 30, 60, 90, 150 minutes after intervention

Method of measurement

Mililiter with use of Peak Flow Meter

3

Description

Peak Expiratory Flow Rate(PEFR)

Timepoint

Before intervention, 30, 60, 90, 150 minutes after intervention

Method of measurement

Mililiter with use of Peak Flow Meter

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before intervention, 30, 60, 90, 150 minutes after intervention

Method of measurement

mmHg

2

Description

Pulse Rate

Timepoint

Before intervention, 30, 60, 90, 150 minutes after intervention

Method of measurement

Rate/Minutes

3

Description

Respiratory Rate

Timepoint

Before intervention, 30, 60, 90, 150 minutes after intervention

Method of measurement

Rate/Minutes

4

Description

Saturation of arterial blood oxygen (SO2 %)

Timepoint

Before intervention, 30, 60, 90, 150minutes after intervention

Method of measurement

Pulse Oximetry

5

Description

Pulsus Paradox

Timepoint

Before intervention, 30, 60, 90, 150 minutes after

intervention

Method of measurement

10 mmHg reduction of blood pressure during inspiration

Intervention groups

1

Description

Intervention Group: (N Salbutamol 2.5 mg + N Ipratropium 0.5 mg) *3 times every 20 min. + 2 tabulate Montolocast 5 mg at 0 min. chew.

Category

Treatment - Drugs

2

Description

Control Group: (N Salbutamol 2.5 mg + N Ipratropium 0.5 mg) *3 times every 20 min. + 2 tabulate Placebo 5 mg at 0 min. chew.Total Patient at 0, 30, 60, 90,150min. After starting the intervention the PEFR and FEV1 should be measured and registered.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Dr. Hasan Motamed

Street address

Ahvaz Golestan Hospital, Golestan

City

Ahvaz

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Hasan Motamed

Street address

Imam Khomeini Hospital , 24 metri street, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Research Assistant, Next to center Building, Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, 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 Golestan Hospital

Full name of responsible person

Dr. Hasan Motamed

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Golestan Hospital, Golestan street, Ahvaz

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Golestan Hospital

Full name of responsible person

Dr. Hasan Motamed

Position

Emergency Medicine Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Golestan Hospital, Golestan street, Ahvaz

City

Ahvaz

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