Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

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

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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