

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of oral Montelukast on lung function and clinical symptoms of asthma exacerbation in Imam Hospital`s patient

Protocol summary

Study aim

evaluation of effect of oral montelukast on pulmonary function improvment

Design

In our research ,140 patients who have entry ceriterion,and coming to sari`s Emam khomeini hospital,coding in basis of table of randum numbers.they divide two group intervention and control.

Settings and conduct

Our research will be done in sari`s Emam khomein hospital.It is be double blind,researcher and events evaluater and patients kept blind.

Participants/Inclusion and exclusion criteria

Known cases of asthma 18 to 65 years old,Who addmit with impression of asthma exacerbatin come into our research.Intubation,other pulmonary disease such as pneumonia,pregnancy and lactation,more than 20 pack/years smoking,phanytoein?phenobarbital and rifampin user`s,hypersansitivity to montelukast are exclude criteria.

Intervention groups

The patients that take oral montelukast and approved treatment of asthma exacerbation, other group,patients thah take placebo tablet in additon to approved asthma exacerbation treatment.

Main outcome variables

Patient`s symptom,physicsl exam.pulmonary function test (FEV1) ,PEFR.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171227038108N1**

Registration date: **2018-01-28, 1396/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-28, 1396/11/08**

Update count: **0**

Registration date

2018-01-28, 1396/11/08

Registrant information

Name

Masoud Alyiali

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral Montelukast on lung function and clinical symptoms of asthma exacerbation in Imam Hospital`s patient

Public title

effect of montelukast in athma exacerbation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 -65 years old Known case of asthma Impersion of asthma exacerbation at time of admision

Exclusion criteria:

Intubation at time of admision Other cause of pulmonary disease for example pneumonia Pregnancy and lactation History of hypersensitivity to montelukast Drug history of phenytoin,rifampin,phenobarbital History of smoking more than 20 pack/years

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients to be coding in bases of Table of random number,then divide to two groups.Control and intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Analyzer coding patients in basis of table of randum numbers.patients,research fellow and avaluator of events kept to blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Siences

Street address

Amirmazandarani Blvd,sari Town

City

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Province

Mazandaran

Postal code

4816633131

Approval date

2017-08-20, 1396/05/29

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1396.3092

Health conditions studied

1

Description of health condition studied

Asthma exacerbation

ICD-10 code

J45.41

ICD-10 code description

Moderate persistent asthma with (acute) exacerbation

Primary outcomes

1

Description

Pulmonary function tast

Timepoint

1,3,5 day's of addmition

Method of measurement

spirometry,peak flowmetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients that treat with montelukast 10 milligram overnight and asthma exacerbation.

Category

Treatment - Drugs

2

Description

Control group: The patients that take placebo tablet in addition to approved asthma exacerbation treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari's Emam hospital

Full name of responsible person

Mahdie Fattahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research and Technology dept of Mazandaran
University Of Medical Science
Full name of responsible person
Majid saeidi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Technology dept of Mazandaran University
Of Medical Science
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Science
Full name of responsible person
Mahdie Fattahi

Position
Internal resident
Latest degree
Medical doctor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

patient dissatisfaction

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

demographic table and questionnaire

When the data will become available and for how long

spring 97

To whom data/document is available

Medical students

Under which criteria data/document could be used

Thesis

From where data/document is obtainable

Emam hospital,Internal group

What processes are involved for a request to access data/document

Academic,official

Comments