Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 addmision

Exclusion criteria:

Intubation at time of addmision Other cause of pulmunary 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

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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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Mo'alem Square
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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
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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
demografic 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