

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing the Effect of Oral Monte Locasta Compared with Pharmacology in Asthma Attacks, In addition to the common treatment of asthma attacks as a two-course, an accident in children aged 1-14 years with asthma

Protocol summary

Study aim

Assess the Effect of Oral Monte Locust Compared with placebo on Asthma Attacks In addition to the common treatment for asthma attacks

Design

Clinical trial with control group, double-blind, randomized, phase three, on 80 patients. Statistical software was also used for randomization

Settings and conduct

The study looked at the effect of oral monte locust in the treatment of acute asthma attacks in addition to the common treatment of asthma in children aged 1-14 years. There were two groups A or B (treatment and control). In addition to the usual treatment for asthma attacks, montelukast chewable tablets were given. The initiation of asthma treatment and the administration of montelukast were assessed for the clinical symptoms of asthma and oxygen-free Saturation O2 in room air. Both placebo and medication were divided into groups A and B. And the Grft.bymar and enforcement executives and other medical staff in the study were blinding.

Participants/Inclusion and exclusion criteria

All children aged 1-14 who have been diagnosed with an asthma attack and who have not taken corticosteroids or monte locusts in the last ten days

Intervention groups

In this intervention, patients were divided into two groups of intervention and control. In addition to the common treatment of asthma in both groups, the drug intervention group was given to the control group and the therapeutic effect was investigated in both groups.

Main outcome variables

Evaluation of the effect of oral monte locust compared to placebo in the treatment of asthma attacks in reducing symptoms during the attack and reducing hospitalization days and reducing the need for hospitalization in the

PICU and also examining this trend in people with a history of atopy and familial disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200412047048N1**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **retrospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Masoomah Sobhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4405 0743

Email address

masoomah.sbh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

2018-04-21, 1397/02/01
Actual recruitment end date
2019-04-30, 1398/02/10
Trial completion date
2019-05-26, 1398/03/05

Scientific title

Assessing the Effect of Oral Monte Locasta Compared with Pharmacology in Asthma Attacks, In addition to the common treatment of asthma attacks as a two-course, an accident in children aged 1-14 years with asthma

Public title

Evaluation of the effect of oral monte locust in the treatment of acute asthma in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients aged 1-14 years who are confirmed based on history and examination for asthma attack

Exclusion criteria:

Those with a history of taking corticosteroids or montelukast for the past ten days All patients who developed a diagnosis other than asthma, such as pneumonia or bronchiolitis

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and their families were explained the study before prescribing the drug, and those who agreed to work were kept blind. The main researcher and the presenter were kept blind until the end of the study and the results were determined. The medical staff (nurses and other physician colleagues) were kept blind to the study. The project manager and statistical officer reviewed the data until the results were blind.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Unit 2, No. 9, Fifth Alley, Ali Hosseini St., Ferdows Shargh Blvd., Sadeghieh,

City

Tehran

Province

Tehran

Postal code

1481957141

Approval date

2019-02-02, 1397/11/13

Ethics committee reference number

IR.TUMS.CHMC.REC.1397.098

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma

Timepoint

At the beginning of the patient's visit, 1,4,8,24,48 hours after the intervention and one week after discharge from the hospital

Method of measurement

Patient scoreboard

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, which included children aged 1-14 years with a diagnosis of asthma attack, Monte Lukast 5 mg / 4.5 tablets for children under 1 year of age

and one complete tablet for children over 5 years of age at the time of the attack and then up to 7 times daily. The day was used. The above medicine was prepared by Obaidi Pharmaceutical Company.

Category

Treatment - Drugs

2**Description**

The control group included children aged 1-14 diagnosed with an asthma attack who were randomly selected and received placebo, which was both the same color and the same size as Monte Lukast. Complete tablets for children over 5 years of age were used during the attack and then daily for up to 7 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bahrami hospital

Full name of responsible person

Masoomeh Sobhani

Street address

Bahrami Children's Hospital., Shahid Kiai St. (Qasem Abad)., not far from Imam Hossein., Damavand St

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masoomeh.sbh@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr.Reza Malekzadeh

Street address

No. 1, Corner of Poursina, Ghods St., Keshavarz Blvd

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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

Tehran University of Medical Sciences

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**

Tehran University of Medical Sciences

Full name of responsible person

Masoomeh Sobhani

Position

Non-faculty physician

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Masoomeh Sobhani

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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