

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of oral magnesium sulfate on moderate and severe asthmatic attack in children aged 5-12 years old referred to emergency department of Ghaem Hospital

Protocol summary

Study aim

The effect of oral magnesium sulfate on moderate and severe asthma exacerbation in children referred to pediatrics emergency department.

Design

This clinical trial, double-blind, control with placebo, single-centered, was performed on 40 asthmatic children.

Settings and conduct

Clinical trial was performed on 40 children aged 5-12 years old with moderate and severe asthmatic exacerbation who referred to Pediatric Emergency Department of Quaem Hospital in Mashhad. Patients were randomly assigned into two groups of Intervention & control groups, received magnesium sulfate or placebo capsules for 5 days.

Participants/Inclusion and exclusion criteria

Inclusion Criteria include acute asthma diagnosis based on history and clinical examination, moderate and severe asthma exacerbation in children aged 5-12 years old with asthma and the consent of the child and his legal guardian to enter the study. Exclusion criteria: mild asthma exacerbation that were curable in an outpatient setting, The presence of chronic underlying disease other than asthma, such as heart, kidney or lung disease, the use of drugs that affect the absorption and secretion mechanism of magnesium including diuretics, digoxin and calcium supplements, Do not taking medication by patient, and Inappropriate follow-up by parents and severe adverse effect of the drug.

Intervention groups

This clinical trial was performed on 40 asthmatic children aged 5-12 years old with moderate and severe asthma exacerbation, if they had inclusion criteria for the study.

Main outcome variables

The dependent variable in this study is the asthma severity score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170915036192N2**

Registration date: **2018-11-27, 1397/09/06**

Registration timing: **retrospective**

Last update: **2018-11-27, 1397/09/06**

Update count: **0**

Registration date

2018-11-27, 1397/09/06

Registrant information

Name

Melika Zarei Sani

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3849 2043

Email address

melika.zareisani@gmail.com

Recruitment status

Recruitment complete

Funding source

personal

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral magnesium sulfate on moderate and severe asthmatic attack in children aged 5-12 years old referred to emergency department of Ghaem Hospital

Public title

The effect of oral magnesium sulfate in asthma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Asthma attack diagnosis based on history and clinical examination of patients diagnosed asthma by asthma specialist. moderate and severe asthma attacks in asthmatic children aged 5 to 12 years. The consent of the child and his legal guardian to enter the study.

Exclusion criteria:

Exclusion criteria: Mild asthma attacks that could be treated on an outpatient basis and at home. The presence of other chronic underlying conditions other than asthma, such as heart disease, renal or pulmonary disease. The use of drugs that affects the magnesium absorption and secretion mechanism include diuretics, digoxin, calcium supplements. Failure to use the drug by the patient and lack of proper follow up by the parent. Severe complications of the drug

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants of the study were selected by convenient sampling from those patients who referred to the emergency department of Ghaem hospital in Mashhad. As these patients arrived they were randomly assigned to one of control or Intervention groups by lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study the pharmacist knew the nature of the drug or placebo while the Investigator and patients were unaware of its nature.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee in medical research of Mashhad University of Medical Sciences

Street address

Azad Square, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

City

Khorasan Razavi

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

IR.MUMS.fm.REC.1395.41

Health conditions studied**1****Description of health condition studied**

astma

ICD-10 code

J45

ICD-10 code description

Asthm

Primary outcomes**1****Description**

Improve the symptoms of asthma

Timepoint

At the time of visit, 2,6,24 hours after the visit, and daily for up to 5 days

Method of measurement

questionnaire

Secondary outcomes**1****Description**

The speed of symptom improvement

Timepoint

When visiting, after 2 hours, 6 hours and 24 hours of referral, and then daily for up to 5 days

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: 300 mg capsules of magnesium sulfate were given to patients in this group every 12 hours for 5 days.

Category

Placebo

2

Description

Control group: Placebo capsules with the same shape, color and smell were given to the patients every 12 hours for 5 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Quaem Hospital

Full name of responsible person

Melika Zarei Sani

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Ahmad Abad St.-Quaem Hospital

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Melika Zarei Sani

Position

Pediatrics resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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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