Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 asthmat 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.modrate 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
quetionnary

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
Street address
Ahmad Abad St.-Quaem Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3845 3239
Email
Quaem.Medical.Center@mums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Melika Zarei Sani
Street address
Azad Square, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 8888
Email
med.faculty@mums.ac.ir
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
Street address
Azad Square, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 8888
Fax
Email
zareism931@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamid Ahanchian
Position
Associated Professor- pediatric Specialist
Latest degree

Subspecialist

Other areas of specialty/work

Immunology

Street address

Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51384000019

Fax

Email

AhanchianH@mums.ac.ir

Web page address

http://www.mums.ac.ir/en

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Melika Zarei Sani

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51384000019

Fax

Email

zareism931@mums.ac.ir

Web page address

http://www.mums.ac.ir/en

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