

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

A clinical trial of the study of the effect of magnesium supplementation on asthma

Protocol summary

Study aim

The aim of this clinical trial is to investigate the effect of magnesium supplements on asthma control.

Design

This is a clinical trial study of patients with severe asthma referring to the specialized lung clinic of Imam Khomeini Hospital in Sari, from October 2016 to October 2018.

Settings and conduct

This study is a double-blind clinical trial that will be performed on patients aged 18-60 years with asthma referring to the specialized lung clinic of Imam Khomeini Hospital in Sari. The randomization method in this randomized study is easy to use, using a random number table. The study included two groups of patients receiving magnesium supplementation and a control group that receives a placebo. The supplement and the placebo are similar and each one receives a code and the patient and distributor of the drug do not know the type of drug and their distribution.

Participants/Inclusion and exclusion criteria

Exclusion criteria: severe asthma, use of oral corticosteroids and diuretics, renal failure, and so on.

Intervention groups

20 mg of magnesium supplement daily and up to 8 weeks for case group. 20 mg placebo daily and up to 8 weeks for the control group.

Main outcome variables

changes in FEV1 / FEC, FVC, FEV1 parameters during study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170827035935N2**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

Babak Mahmoodi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 937 114 3879

Email address

h.jafarpour@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the study of the effect of magnesium supplementation on asthma

Public title

The effect of magnesium in controlling asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with asthma

Exclusion criteria:

Use of oral corticosteroids Use Diuretics Renal failure
Congestive heart failure Use of magnesium supplement
in the past quarter History of using cigarettes Pregnancy
The decision to have a pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this randomized study is easy randomization. Patients will be placed in two groups of control (non-supplement magnesium) and the case group (magnesium supplements recipient) using a randomized table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will not be aware of any kind of medication (magnesium supplement or placebo), and the investigator will not know whether each patient receives medication or placebo. The placebo is completely white in the form of pills. It is a homogeneous with complementary magnesium supplement that is provided by the Faculty of Pharmacy of Mazandaran University of Medical Sciences. Magnesium supplement is purchased in the number of intervention group and code A is written by the clinical pharmacist on the pill. The placebo is provided for the control group and code B is written by the pharmacist of the study on the container. The patient and researcher responsible for distributing the medicine are not aware of the type of medicine and their distribution.

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 Sciences

Street address

Deputy of research and technology, Moalem Sq

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2017-08-19, 1396/05/28

Ethics committee reference number

IR.MAZUMS.IMAMHOSIPTAL.REC.96.2886

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.9,J46

ICD-10 code description

Asthma, unspecified, Acute severe asthma

Primary outcomes

1

Description

Severity of asthma

Timepoint

At the beginning of the study (before the intervention) and at weeks 4, 8 and 12 after the intervention

Method of measurement

PEFR measurements by peak flow meter

2

Description

FEV1/FVC

Timepoint

Before and immediately after the intervention

Method of measurement

Spirometry

3

Description

The number of asthma attacks

Timepoint

At the beginning of the study (before the intervention) and at weeks 4, 8 and 12 after the intervention

Method of measurement

Ask the patient

4

Description

ACT-Score

Timepoint

At the beginning of the study (before the intervention) and at weeks 4, 8 and 12 after the intervention

Method of measurement

ACT questionnaire

5

Description

FEV1

Timepoint

Before and immediately after the intervention

Method of measurement

Spirometry

6

Description

FVC

Timepoint

Before and immediately after the intervention

Method of measurement

Spirometry

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Magnesium Supplement with Brand Magne B6, product of Sanofi Aventis Pharmaceutical Factory, containing 470 mg of lactate magnesium, equivalent to 48 mg of magnesium, begins twice a day and will be used as a preservative for up to 8 weeks on a daily basis.

Category

Treatment - Drugs

2

Description

Control group: The Placebo made by pharmaceutical faculty of the Mazandaran University of Medical Sciences will be used twice a day and as a preservative for up to 8 weeks on a daily basis.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized Clinic of Imam Khomeini Hospital

Full name of responsible person

Babak Mahmoodi

Street address

Imam Khomeini Educational Center, Razi St.

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3336 1700

Email

hamed.jafarpour7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Science

Full name of responsible person

Majid Saeidi

Street address

Vice chancellor for research, Mazandaran University of Medical Science, Moalem Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3326 1249

Email

hamed.jafarpour7@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research 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

Dr. Ali Sharif Pour

Position

Asociated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Internal Medicine Departmnt, Imam Khomeini Hospital

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3448 4864

Fax**Email**

hamed.jafarpour7@gmail.com

Web page address

hamed.jafarpour7@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Babak Mahmoodi

Position

Residency

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Payambar Azam Campus, Km 17 on Farah Abad road

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3448 4864

Fax**Email**

hamed.jafarpour7@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Babak Mahmoodi

Position

Residency

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Payambar Azam Campus, Km 17 on Farah Abad road

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3448 4864

Fax**Email**

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