

# 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

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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

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

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Internal Medicine Departmnt, Imam Khomeini Hospital

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Position**  
Residency

**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
Internal Medicine

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Payambar Azam Campus, Km 17 on Farah Abad road

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## Person responsible for updating data

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**Position**  
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Medical doctor

**Other areas of specialty/work**  
Internal Medicine

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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