

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Effect of oral magnesium supplement on lung function in patients with asthma

#### Protocol summary

##### Summary

Asthma is the most common chronic medical condition that leads to serious health and economic consequences. There is evidence that high intake of magnesium is effective on pulmonary function, and reduce sensitivity of bronchial. Most assessments of asthma based on symptoms and lung function testing , Quality of life is a concept that has recently been considered in the management of asthma. The purpose of this study was to evaluate the effect of oral magnesium supplementation on lung function, quality of life, asthma control and inflammatory factors in adult patients with asthma . Methods: In this double- blind clinical trial, 100 patients (53 male, 47 female), 19-55 years old with asthma were randomly assigned to two groups. Group supplemented daily received 2 capsuls 150 mg magnesium citrate and placebo groups received 2 capsules contain lactose, in addition to standard asthma treatment for 2 months. Serum magnesium levels, quality of life, asthma control, IL-17 and spirometric parameters were measured at the beginning and end of the study. IL-17 levels were determined by ELISA.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2012102811285N1**

Registration date: **2015-05-18, 1394/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-18, 1394/02/28

##### Registrant information

##### Name

Narges Fathi

##### Name of organization / entity

Jundishapur university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1333 7168

##### Email address

fathi.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University

##### Expected recruitment start date

2012-05-31, 1391/03/11

##### Expected recruitment end date

2012-10-01, 1391/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of oral magnesium supplement on lung function in patients with asthma

##### Public title

Clinical trial on effect of oral magnesium supplement on lung function in patients with asthma

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Men and women 19 to 55 years of age who met the Global Initiative for Asthma (GINA) guidelines in 2008, FEV1more than80%, variability FEV1less than 20-30% for mild asthma and FEV1=60-80%, variability FEV1more than 30% for

moderate asthmatic; non smoker; who used only beta-agonist or inhaled corticosteroids. Exclusion criteria: evidence of cardiovascular disease, abnormal kidney function, other lung disease; alcohol abuse; uncontrolled hypertension; pregnancy or breastfeeding; have any change in own diet; current use of theophylline or leukotriene antagonists; any treatment likely to affect magnesium absorption or excretion, including diuretics or calcium containing medications; history of emergency room care or hospitalization for asthma in the last 6 months.

#### Age

From **19 years** old to **55 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Single

#### Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Abadan International Unit of Jundishapur University

##### Street address

Iran, Abadan, Infront of Abadan International University

##### City

Abadan

##### Postal code

393/61355

#### Approval date

2012-05-30, 1391/03/10

#### Ethics committee reference number

517- ETH

## Health conditions studied

### 1

#### Description of health condition studied

Asthma

#### ICD-10 code

x

#### ICD-10 code description

chronic lower respiratory disease

## Primary outcomes

### 1

#### Description

Force Vital Capacity

#### Timepoint

before intervention and two months after the intervention

#### Method of measurement

based on litter with spirometry

### 2

#### Description

Forced expiratory volume in one second

#### Timepoint

before intervention and two months after the intervention

#### Method of measurement

based on %liter with spirometry

### 3

#### Description

Density of interlukine 17 in blood

#### Timepoint

before intervention and two months after the intervention

#### Method of measurement

based on pico grams per milliliter with laboratory kit

### 4

#### Description

FEV1/FVC

#### Timepoint

before intervention and two months after the intervention

#### Method of measurement

with spirometry

## Secondary outcomes

### 1

#### Description

magnesium concentration in serum

#### Timepoint

before intervention and two months after intervention

#### Method of measurement

based on mg/dl with laboratory kit

## 2

### **Description**

level of magnesium intake

### **Timepoint**

three times (two days and one weekend)

### **Method of measurement**

based on mg/d with 24 hours intake for three times

## 3

### **Description**

levels of quality of life

### **Timepoint**

before intervention and two months after intervention

### **Method of measurement**

numbers of quality of life quationnaire

## 4

### **Description**

level of asthma control

### **Timepoint**

before intervention and two months after intervention

### **Method of measurement**

numbers of asthma control quationnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group:citrate magnesium,capsules 150 mg oral twice a day for two months

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Contol group:placebo,150 mg capsules oral lactose, twice a day for two months

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Lung Clinic of Ahwaz Imam Khomeini Hospital

##### **Full name of responsible person**

Doctor Heshmat Alah Tavakol lung Disease Specialist

##### **Street address**

Ahwaz, Naderi

##### **City**

Ahwaz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Abadan International Unit Of Ahwaz Jundishapur University

##### **Full name of responsible person**

Doctor Nader Saki

##### **Street address**

Flat three, Number 119, West Mordad avenue, Kian Pars, Ahwaz, Iran

##### **City**

Ahwaz

#### **Grant name**

طرح تحقیقاتی مصوب معاونت پژوهشی دانشگاه علوم پزشکی جندی شاپور

#### **Grant code / Reference number**

9109-B

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

Yes

#### **Title of funding source**

Abadan International Unit Of Ahwaz Jundishapur University

#### **Proportion provided by this source**

100

#### **Public or private sector**

*empty*

#### **Domestic or foreign origin**

*empty*

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Abadan International Unit of Ahwaz Jundishapur University

##### **Full name of responsible person**

Narges Fathi

##### **Position**

Graduate Student Of Nutrition

##### **Other areas of specialty/work**

##### **Street address**

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##### **Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahwaz Jundishapur University

**Full name of responsible person**

Seid Ahmad Hosseini

**Position**

Doctor of Biochemistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*