

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effects of magnesium supplement on muscle strength, muscle function, and inflammatory markers in middle-aged women.

Protocol summary

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Summary

We have designed a double-blind, placebo-controlled, randomized trial to investigate whether magnesium supplementation improves muscle function, strength and inflammatory state. Eighty women, aged 45-55 years old, stopped menstrual cycle for at least 12 month, who is eligible for this study, will be recruited from Iran medical university. Participants will be divided in two groups randomly, receiving either 250 mg magnesium in the form of magnesium Oxide or placebo for 8 weeks. Handgrip strength, Knee extension strength and time get up and go test (muscle strength and function markers), IL-6, hs-CRP, and fibrinogen (inflammatory markers) will be measured at the baseline and the end of the study.

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Iran University of Medical Sciences

Expected recruitment start date

2009-11-26, 1388/09/05

Expected recruitment end date

2010-03-06, 1388/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805312365N1**

Registration date: **2010-01-09, 1388/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-09, 1388/10/19

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4734

Email address

Scientific title

The effects of magnesium supplement on muscle strength, muscle function, and inflammatory markers in middle-aged women.

Public title

The effects of magnesium supplement on muscle strength, muscle function, and inflammatory markers in middle-aged women.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age 45 to 55 years old 2. Stopped menstrual cycle for at least 12 month 3. Voluntary participation Exclusion criteria: 1. BMI less than 25 Kg/m² 2. Having one of the following diseases: uncontrolled hypertension, Diabetes, cardiovascular diseases, asthma, Thyroid or parathyroid diseases, renal disorders, liver diseases, bone or rheumatoid disorders, gastrointestinal diseases, and infectious diseases 3. Taking any supplements including minerals, vitamins, and ω-3 fatty acids 4. Receiving hormonal products 5. Cigarette smoking 6. Using one of the following

medications: anti-inflammatory drugs (including NSAIDs, steroids, salicylates), aminoglycosides antibiotics, Laxative drug, magnesium-containing drugs 7. compliance less than 70%

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of health, Iran university of Medical Sciences

Street address

school of Health, Arjantin Square, Alvand Ave., Tehran

City

Tehran

Postal code

1516846514

Approval date

empty

Ethics committee reference number

2155/پ/5/26د

Health conditions studied

1

Description of health condition studied

Decrease of muscle strength

ICD-10 code

M62.5

ICD-10 code description

Muscle wasting and atrophy, not elsewhere classified

Primary outcomes

1

Description

Muscle strength in hand and foot

Timepoint

8 weeks

Method of measurement

Dynamometer, Handgrip

Secondary outcomes

1

Description

Inflammatory markers

Timepoint

8 weeks after intervention

Method of measurement

decline of inflammatory marker

Intervention groups

1

Description

Dietary Magnesium supplement, 250 mg, for 8 weeks

Category

Prevention

2

Description

Placebo, the same tablets as the active drug with the same dose for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Street address

school of health, Arjantin square, Alvand Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran Univesity of Medical Sciences

Full name of responsible person

Dr Mohsen Asadi Lari

Street address

Iran University of Medical Sciences, Hematt express way,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Univesity of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Associate Professor

Other areas of specialty/work

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rezavafa@iums.ac.ir, rezavafa@yahoo.com

Web page address

Person responsible for updating data

Contact

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