Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

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

Protocol summary

Study aim
Resolving the deficiency of vitamin D and magnesium in order to improvement of muscle strength, muscle function, and inflammatory markers in middle-aged women

Design
A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 90 participants , enrolled between March 2018 and November 2018

Settings and conduct
1.90 employer from age of 40 to 55 in all of campuses of Iran University will be participated in randomized double blind placebo-controlled trial.2.10 cc blood vein will be taken, anthropometric variables and muscle strength in hand and foot will be measured.3.The intervention group will receive 250 mg per day and 50000 IU vitamin D per month.The control group will receive the placebo of them.

Participants/Inclusion and exclusion criteria
Middle-aged women working in Iran University Of Medical Science and subsidiary health centers who has expressed the willingness to cooperate,Aged 40-55 years old,BMI more than 25 kg/m2 and serum vitamin D levels less than 25 ng/ml/ In case of pregnancy and breastfeeding,having chronic disease,taking any supplements at least in the last 3 months and cigarette smoking the volunteers will not enter to study.

Intervention groups
Middle-aged women working in Iran University Of Medical Science and subsidiary health centers who has the inclusion criteria and expressed the willingness to cooperate

Main outcome variables
Improvement of muscle strength in hand and foot

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090822002365N20**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date
2018-03-10, 1396/12/19

Registrant information

Name
Mohammad Reza Vafa

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8670 4734

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vafa.m@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-11-06, 1397/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of magnesium and vitamin D supplement on muscle strength, muscle function, and inflammatory

markers in middle-aged women.

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

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Voluntary participation Age from 40 to 55 years old BMI>=25kg/m2 Having serum vitamin D less than 30 ng/ml

Exclusion criteria:

Age
From **40 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 90 subjects, 23 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug boxes that is generated by the software. Participants will enter based on the sequence produced into study and the drug packets with code registered will allocate to the individual. Therefore, before participants selection, they will be unaware of the type of intervention that will receive, as well as a random sequence produced during the study will be immune from prediction.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to performing the double-blinded of study, before study beginning, the canisters containing tablets can be provided by someone other than the researcher, and the placebo tablets in appearance are similar to the supplementation tablets and the researcher are not be aware about the allocation of studied subjects in each group during the evaluation of the studied outcomes until the end of the intervention period.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Science

Street address
Hemmat Express way, Iran University of Medical Science

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2017-10-27, 1396/08/05

Ethics committee reference number
IR.IUMS.FMD.REC 1396.9413468001

Health conditions studied

1

Description of health condition studied
Sarcopenia, muscle weakness, decrease of muscle strength

ICD-10 code
M62.5

ICD-10 code description
Muscle wasting and atrophy ,not elsewhere classified

Primary outcomes

1

Description
Improvement of muscle strength in hand and foot

Timepoint
Before the intervention and two months later of intervention

Method of measurement
Dynamometer, Handgrip

Secondary outcomes

1

Description
hs-CRP

Timepoint
Before the intervention and two months later of intervention

Method of measurement
immunoturbidimetry

2

Description
TNF-α
Timepoint
Before the intervention and two months later of intervention
Method of measurement
Concentration of TNF-α in serum using ELISA kit

3

Description
IL-6
Timepoint
Before the intervention and two months later of intervention
Method of measurement
Concentration of IL-6 in serum using ELISA kit

Intervention groups

1

Description
Intervention group: Daily intake of one magnesium supplement (250 mg) and weekly intake of vitamin D (50000 IU) for 8 weeks (2 months)
Category
Treatment - Drugs

2

Description
Control group: Daily intake of one placebo magnesium tablet (containing Maltodextrin) and weekly intake of one vitamin D tablet (containing Maltodextrin) for 8 weeks (2 months)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran University of Medical Science
Full name of responsible person
Mohammad Reza Vafa
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Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehranan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
personal (expenses will payed by student)
Full name of responsible person
Fatemeh Kheyruri
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nkheiruri@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
personal (expenses will payed by student)
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical science
Full name of responsible person
Mohammad Reza Vafa
Position
PhD of Nutrition science
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only a section of the data, such as primary outcomes information or the like, will be shared.
When the data will become available and for how long
Access period start 6 months after results publishing
To whom data/document is available
The obtained data from current study will be available only for working researchers in academic and scientific institutions
Under which criteria data/document could be used
Six months after the publicated papers from this study, the obtained data will be available to the researchers for further analysis
From where data/document is obtainable
Applicants can be communicated to correspond author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of Public Health, Iran university of Medical Sciences, Hemat Express way, Tehran Cell phone:+98 21 8670 4743 Email:vafa.m@iums.ac
What processes are involved for a request to access data/document
Applicants will be given access to the obtained data from current study by sending an email to the correspond author
Comments