Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of magnesium and omega 3 co-supplementation on muscle strength, physical performance, muscle mass, inflammation, and intrinsic capacity index in elderly with sarcopenia: A double-blind randomized placebo-control trial

Protocol summary

Study aim
Determining the effect of magnesium and omega 3 co-supplementation on muscle strength, physical performance, muscle mass, inflammation, and intrinsic capacity index in elderly with sarcopenia

Design
A two-arm, parallel double-blind, controlled randomized clinical trial of 66 patients. block method was used for randomization.

Settings and conduct
This study will be conducted in nursing homes and elderly care centers in Tehran. Inclusion criteria included relatively healthy participants without acute illness and over 60 years of age who completed sarcopenia screening and the ICOPE screening assessment. Data collecting and conducting random allocation will be done according to the orders already provided by a statistician. Intervention and placebo packages will be in the same containers with labels "A" or "B" provided by a non-involved faculty, so both subjects and assessors will be blinded to the intervention type.

Participants/Inclusion and exclusion criteria
66 relatively healthy elderly will be selected. The inclusion criteria are as follows: age>60 years, diagnosis of possible sarcopenia, impaired intrinsic capacity. Exclusion criteria were: Acute cardiovascular diseases, acute infection, and acute cerebrovascular disease, unable to provide informed consent, disability

Intervention groups
The intervention group will receive 1 tablet containing 250 mg of elemental magnesium and 1 Capsule containing 1000 mg omega-3 [each capsule containing 180 mg eicosapentaenoic acid (EPA) and 120 mg .docosahexaenoic acid (DHA)] daily for 8 week

Main outcome variables
Determining muscle strength, physical performance, muscle mass, inflammation, and intrinsic capacity index following magnesium and omega 3 co-supplementation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090822002365N30**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date
2024-06-22, 1403/04/02

Registrant information

Name
Mohammad Reza Vafa

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of magnesium and omega 3 co-supplementation on muscle strength, physical performance, muscle mass, inflammation, and intrinsic capacity index in elderly with sarcopenia: A double-blind randomized placebo-control trial

Public title
Effect of magnesium and omega 3 co-supplementation supplement in Sarcopenic Elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Complete and sign informed consent Age 60-84 years Diagnosis of possible sarcopenia according to update of Asian Working Group for Sarcopenia (AWGS) (hand grip strength less than 28 kg in men and less than 18 kg in women) Impaired intrinsic capacity according to the first step of ICOPE guidelines of the World Health Organization Required no or some support with self-care (feeding, bathing, dressing, toileting). Taking any supplements containing magnesium and omega-3 during the last 2 months Taking any supplements containing more than 100 mg magnesium
Exclusion criteria:
Acute cardiovascular diseases, acute infection, and acute cerebrovascular disease Severe cardiac, liver, kidney dysfunction, autoimmune Uncontrolled diabetes Dementia, Parkinsons disease, and mental illnesses unable to provide informed consent because of aphasia, deafness, and blindness Physically-handicapped, disability, and use of a wheelchair or walker Taking hormonal drugs smoking Acute illness (cold, corona and any other viral-bacterial-fungal disease) Taking steroidal and non-steroidal anti-inflammatory drugs, aminoglycoside antibiotics, laxatives and laxatives
Age
From **60 years** old to **84 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocating samples to intervention and placebo groups will be done using the block method with blocks 4 and 6.
Blinding (investigator's opinion)
Double blinded
Blinding description
To hide the random allocation, unique codes will be used on the supplement cans and the desired code will be generated by the software and will be done by the sealed envelope method with a random sequence. Allocation is done by someone who is outside the study. As each person enters the study based on the generated sequence, the supplementary package in which the desired code is recorded will be assigned to the person, and therefore, before choosing the person, no one will be aware of the type of treatment he will receive. Also, the person evaluating the patient will not be aware of the intervention.
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 Sciences
Street address
Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2024-06-02, 1403/03/13
Ethics committee reference number
IR.IUMS.REC.1403.208

Health conditions studied

1

Description of health condition studied
Sarcopenia
ICD-10 code
M62.5
ICD-10 code description
Muscle wasting and atrophy, not elsewhere classified

2

Description of health condition studied
Intrinsic capacity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Muscle strength
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Handgrip strength

2

Description
Muscle function
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Short Physical Performance Battery (SPPB)

3

Description
Muscle mass
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Bioelectrical Impedance Analysis (BIA)

4

Description
Inflammation
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
The level of CRP and ESR in serum

5

Description
intrinsic capacity index
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Short Physical Performance Battery (SPPB), Mini-mental state examination(MMSE), Patient Health Questionnaire-9(PHQ-9), WHISPER test, WHO simple eye chart, Mini nutritional assessment (MNA)

Secondary outcomes

1

Description
Frailty
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
The Fried phenotype (FP)

Intervention groups

1

Description
Intervention group: 33 elderly receive one tablet of 250 mg of magnesium supplement and 1000 mg of omega 3(120 mg EPA and 180 mg DHA) daily for 8 weeks each.
Category
Treatment - Other

2

Description
Control group: 33 elderly, each receiving 1 placebo magnesium tablet and 1 placebo omega 3 capsule daily for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
kahrizak charity fundation
Full name of responsible person
kahrizakcharity fundation
Street address
Tehran, Old Qom Road, after Behesht Zahra (S), Kahrizak, at the end of Kahrizak, Dr. Hakimzadeh Blvd.
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Sponsors / Funding sources

1

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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
Iran University of Medical Sciences
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
Iran University of Medical Sciences
Full name of responsible person
Mohammad Reza Vafa
Position
Professor
Latest degree
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Other areas of specialty/work
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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

A part of the data will be shared, such as primary outcomes.

When the data will become available and for how long

Four months after the publication of the results

To whom data/document is available

Researchers and students of university

Under which criteria data/document could be used

Four months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Department of nutrition, school of health, Iran university of medical sciences, Hemmat highway, Tehran. Phone number: 0098 21 86704743. E-mail: vafa.m@iums.ac.ir

What processes are involved for a request to access data/document

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Department of nutrition, school of health, Iran university of medical sciences, Hemmat highway, Tehran. Phone number: 0098 21 86704743. E-mail: vafa.m@iums.ac.ir

Comments