

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of magnesium and synbiotic supplementation on cognitive function, quality of life, frailty and serum level of the inflammatory index high-sensitivity C - reactive protein in the older adults with mild cognitive impairment

Protocol summary

Study aim

Comparison of the effect of magnesium and synbiotic supplementation on cognitive function, quality of life, frailty and serum level of the inflammatory index high-sensitivity C - reactive protein in the older adults with mild cognitive impairment

Design

A clinical trial with control group, double-blind, randomized, parallel-group on 63 participants. Random Allocation Software was used for randomization.

Settings and conduct

Participants will be selected by a simple random sampling from Farzanegan senior center in Shiraz; after screening and confirming the disease and if they meet the study entry criteria, the informed consent form will be completed. Participants will be placed in one of three groups: magnesium intervention, synbiotic, and placebo by a random block method. Outcomes will be evaluated at the beginning and end of the study. The duration of the intervention is 8 weeks. Also, in this study, participants and the researcher will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: age 65 years and older, mild cognitive impairment, no severe renal/liver/pulmonary insufficiency, no uncontrolled diabetes, no severe neurological or psychiatric disorders, no adherence to special diets, no current use of medications that interact with magnesium. Exclusion criteria included changes in usual diet and medication, initiation of antibiotic therapy, occurrence of any side effects that stopped with discontinuation of the intervention, adherence of less than 80% and unwillingness to continue cooperation.

Intervention groups

Eligible people are placed in one of the following groups by random blocking method: group1: taking a capsule containing 300 mg of elemental magnesium daily. Group

2: taking a synbiotic capsule daily. Group 3: taking a placebo

Main outcome variables

Cognitive function, quality of life, frailty, serum level of the inflammatory index hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250317065109N1**

Registration date: **2025-04-02, 1404/01/13**

Registration timing: **prospective**

Last update: **2025-04-02, 1404/01/13**

Update count: **0**

Registration date

2025-04-02, 1404/01/13

Registrant information

Name

Rahil Ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5357 9434

Email address

rahilranjbar9@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-09-22, 1404/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of magnesium and synbiotic supplementation on cognitive function, quality of life, frailty and serum level of the inflammatory index high-sensitivity C - reactive protein in the older adults with mild cognitive impairment

Public title

Comparison of the effect of magnesium and synbiotic supplementation on cognitive function, quality of life, frailty and inflammation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 65 years and older Suffering from mild cognitive impairment; means obtaining a score of 22 to 25 in the Mini-ACE cognitive function evaluation form Ability and willingness to participate in the study No smoking/alcohol and drug addiction Absence of severe renal/hepatic/pulmonary insufficiency, uncontrolled diabetes, severe neurological or psychiatric disorders such as Bipolar disorder, Parkinson's disease, Dementia, unstable thyroid disease; Immune disorders such as HIV/AIDS Not following specific diets (such as Ketogenic, Vegetarian, etc.) No current use of medications that interact with magnesium, such as muscle relaxants, Penicillamine, Corticosteroids, Methyldopa, Magnesium-containing antacids, or other magnesium-containing products Participants must have not taken antibiotics and probiotic, magnesium, and antioxidant supplements for at least 2 weeks prior to the start of the study

Exclusion criteria:

Changes in usual diet and medication Starting antibiotic therapy The occurrence of any side effects that stops when the intervention is discontinued. Less than 80% adherence to supplement use Unwillingness to continue cooperation

Age

From 65 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 63

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to three groups: magnesium intervention, synbiotic intervention, and control (A, B, C) based on the random blocking method using the Random Allocation Software with a ratio of 1:1:1. This group assignment will be done by a person outside the study before the start of the design implementation process, and these sequences will be placed in sealed numbered envelopes by the same person in order to blind the researchers to the participant group by concealing the allocation. After screening with a cognitive function assessment questionnaire and confirmation of mild cognitive impairment, participants will be referred to the research team and the thesis supervisor. After completing the evaluations and the initial questionnaires, an envelope will be opened according to the established order, and the assigned intervention group will be determined for the participating individual. This randomization and groups will remain hidden from the researchers and participants until the statistical analysis are complete.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the first phase of the study, the supplements and placebo are placed in capsules that are similar in color, size, and shape and packaged. In this phase, the capsules are labeled with the Latin contract names A, B, and C. In the intervention phase, the random assignment sequence is also identified with the same names by a person outside the study. Therefore, during the study, the participants and the student implementing the project, who is in charge of carrying out the clinical phase, clinical evaluations, follow-up of laboratory tests and data analysis, will be blinded to the assigned group and the intervention in each group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences Central Building, in front of Palestine, Zand Street

City

Shiraz

Province

Fars

Postal code
7134814336
Approval date
2025-02-16, 1403/11/28
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1403.119

Health conditions studied

1

Description of health condition studied

Mild cognitive impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Cognitive function score in the Mini-Addenbrooke's
Cognitive Examination (M-ACE) questionnaire

Timepoint

Cognitive function assessment before the start of the
intervention and 8 weeks later (end of the study)

Method of measurement

Mini-Addenbrooke's Cognitive Examination (M-ACE)
questionnaire

2

Description

Serum level of high-sensitivity C-reactive protein

Timepoint

Measurement of serum levels of high-sensitivity C-
reactive protein before the start of the intervention and 8
weeks later (end of study)

Method of measurement

Through a blood test and ELISA method

Secondary outcomes

1

Description

Quality of life score in the Older People's Quality of Life
questionnaire (OPQOL-brief)

Timepoint

Quality of life assessment before the start of the
intervention and 8 weeks later (end of the study)

Method of measurement

Older People's Quality of Life questionnaire-brief version
(OPQOL-brief)

2

Description

Frailty score in the Frailty Syndrome Checklist 5-Items in
Frail Older Adults in Iran (Fried's Five-Point Frailty Test)

Timepoint

Frailty assessment before the start of the intervention
and 8 weeks later (end of the study)

Method of measurement

Frailty score in the Frailty Syndrome Checklist 5-Items in
Frail Older Adults in Iran (Fried's Five-Point Frailty Test)

Intervention groups

1

Description

First intervention group: In this group, individuals will
receive one capsule containing 300 mg of elemental
magnesium (500 mg of magnesium in the form of
magnesium oxide) daily for 8 weeks. Magnesium
supplements will be prepared from Jalinous
Pharmaceutical Company in the form of magnesium
oxide powder and encapsulated by Shiraz Faculty of
Pharmacy.

Category

Treatment - Other

2

Description

Second intervention group: In this group, individuals will
receive one synbiotic capsule daily for 8 weeks. The
synbiotic supplement will be provided in capsule form by
the Zist Takhmir Pharmaceutical Company (Famifact®).
This supplement contains 109 CFU of probiotics including
Lactobacillus plantarum, Lactobacillus rhamnosus,
Lactobacillus acidophilus, Lactobacillus casei,
Bifidobacterium breve, Bifidobacterium longum,
Bifidobacterium lactis, Bifidobacterium bifidum,
Streptococcus thermophilus, and 74 mg of
fructooligosaccharide in synbiotic form.

Category

Treatment - Other

3

Description

Control group: In this group, individuals will receive a
placebo in capsule form that is similar in appearance to
the intervention group for 8 weeks. Also, the placebo will
be provided in capsule form by Zist Takhmir
Pharmaceutical Company. The content of the placebo will
be mostly maltodextrin and lactose monohydrate.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farzanegan Senior Center, Shiraz

Full name of responsible person

Shahzad Etemad

Street address

four hundred meters after the Science and Technology Park, Fanavari Street, end of Arian Town, Sanayi Blvd. (Mirza Shirazi, Dr. Hesabi Alley 22), Shiraz

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Web page address

<https://www.farzanegan24.com>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

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Shiraz University of Medical Sciences central building, in front of Palestine St., Zand St.

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Web page address

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Grant name

Performance-based grant

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Rahil Ranjbar

Position

Master's degree student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Afsane Ahmadi

Position

Assistant professor, Faculty member / School of Nutrition and Food Sciences / Shiraz University of M

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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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