Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on insulin resistance, inflammatory factors, biomarkers of oxidative stress and cognitive function in patients with Alzheimer's disease

Protocol summary

Study aim

The aim of this study is to determine the effects of combined probiotic and selenium supplementation on insulin resistance, inflammatory factors, biomarkers of oxidative stress and cognitive function in patients with Alzheimer's disease.

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Golabchi Welfare Organization (Kashan, Iran) Madar, Shayestegan and Amin Welfare Organizations (Shahrekord, Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Alzheimer's disease and aged 55 to 100 years will be included in this study. Exclusion criteria: Patients with metabolic syndrome, diabetes, cardiovascular disease, chronic infections, consuming probiotic and/or synbiotic supplements within 8 weeks prior to the study, taking other forms of probiotics including probiotic yogurt and other fermented foods, and taking antioxidants supplements will be excluded.

Intervention groups

Patients will be assigned to receive selenium supplements (n=30)and combined probiotic and selenium supplementation (n=30) and placebo (n=30).

Main outcome variables

Fasting blood samples will be taken at baseline and after 12-week intervention and insulin resistance, inflammatory factors and biomarkers of oxidative stress, and cognitive function will be measured at baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170612034497N5**
Registration date: **2018-04-02, 1397/01/13**
Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **2**

Registration date

2018-04-02, 1397/01/13

Registrant information

Name

Omid Reza Tamtaji

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 5562 1157

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tamtaji-or@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-29, 1396/10/08

Expected recruitment end date

2018-01-29, 1396/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of combined probiotic and selenium supplementation compared with the placebo on insulin resistance, inflammatory factors, biomarkers of oxidative stress and cognitive function in patients with Alzheimer's disease

Public title
Effect of combined probiotic and selenium supplementation in treatment of patients with Alzheimer's disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Alzheimer's disease Individuals aged 55 to 100 years

Exclusion criteria:
Patients with metabolic syndrome Patients with diabetes Patients with cardiovascular disease Patients with chronic infections Consuming probiotic and/or synbiotic supplements within 8 weeks prior to the study Taking other forms of probiotics including probiotic yogurt and other fermented foods Taking antioxidants supplements

Age
From **55 years** old to **100 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after stratification for pre-intervention BMI and age subjects will be randomly divided into three groups to take either selenium supplements + probiotic placebos (n = 30) or selenium and probiotic supplements (n = 30) or selenium and probiotic placebos (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2017-12-28, 1396/10/07

Ethics committee reference number
IR.Kaums.REC.1396.65

Health conditions studied

1

Description of health condition studied
Alzheimer's disease

ICD-10 code
G30

ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description
Cognitive function

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Mini Mental State Exam (MMSE)

Secondary outcomes

1

Description
Total cholesterol

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
ELISA kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
ELISA kit

6

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Fasting blood sugar
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

11

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

Intervention groups

1

Description
Intervention group: Probiotic oral capsule containing four strains of Lactobacillus acidophilus (2×109 CFU/g), Bifidobacterium lactis (2×109 CFU/g), Bifidobacterium bifidum (2×109 CFU/g) and bifidobacterium longum (2×109 CFU/g) and selenium (200 µg), daily, for 12 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Oral capsule containing selenium (200 µg), daily, for 12 weeks.
Category
Treatment - Drugs

3

Description
Control group: Placebo oral capsule, daily, for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golabchi Welfare Organization
Full name of responsible person
Zatollah Asemi
Street address
Fine bozorg Ave, Kashan
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2

Recruitment center
Name of recruitment center
Shayestegan Welfare Organization
Full name of responsible person
Zahra Hosseini
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3

Recruitment center
Name of recruitment center
Madar Welfare Organization
Full name of responsible person
Fariba Jafarian
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4

Recruitment center
Name of recruitment center
Amin Welfare Organization
Full name of responsible person
Reza Heidari-Soureshjani
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
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hamidi_gh@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Omid Reza Tamtaji

Position

MSc student in medical physiology

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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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