Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on cognitive function and metabolic profiles in patients with Alzheimer's disease

Protocol summary

Study aim
The aim of this study is to determine the effects of probiotic supplementation on cognitive function and metabolic profiles in patients with Alzheimer's disease.

Design
Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct
60 patients with Alzheimer's disease of eligible at Golabchi (Kashan, Iran) and Sadeghyeh (Esfahan, Iran) Welfare Organizations in the study will be selected.

Participants/Inclusion and exclusion criteria
Patients with Alzheimer's disease and aged 60 to 95 years will be included in this study. Patients with metabolic disorders, chronic infections and/or other clinically relevant disorders with exception of AD and consuming probiotic supplements within 6 weeks prior to the study, taking other forms of probiotics including probiotic yogurt, kefir, and other fermented foods will excluded.

Intervention groups
Patients will be assigned to receive either probiotic supplements (intervention group: n=30) and placebo (control group: n=30).

Main outcome variables
Cognitive function and metabolic profiles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201511305623N60**
Registration date: **2015-12-01, 1394/09/10**
Registration timing: **retrospective**

Last update: **2019-09-18, 1398/06/27**
Update count: **1**

Registration date
2015-12-01, 1394/09/10

Registrant information

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Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2015-10-24, 1394/08/02

Expected recruitment end date
2015-11-01, 1394/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of probiotic supplementation compared with the placebo on cognitive function and metabolic profiles in patients with Alzheimer's disease

Public title
Effect of supplementation in treatment of patients with Alzheimer's disease

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Alzheimer's disease Aged 60 to 95 years
Exclusion criteria:
Patients with metabolic disorders Patients with chronic infections and/or other clinically relevant disorders Consuming probiotic supplements within 6 weeks prior to the study Taking other forms of probiotics including probiotic yogurt, kefir, and other fermented foods
Age
From **60 years** old to **95 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
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 two groups to take either probiotic supplements (n = 30) or placebo (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 at the Welfare Organizations, 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
Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Approval date
2015-10-24, 1394/08/02
Ethics committee reference number
IR.Kaums.REC.1394.97

Health conditions studied

1

Description of health condition studied
Alzheimer's disease
ICD-10 code
F00
ICD-10 code description
Dementia in Alzheimer 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
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

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

5

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

6

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

7

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

8

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

9

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

10

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

11

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

12

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 supplements containing four strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g), Bifidobacterium bifidum (2×109 CFU/g) and Lactobacillus fermentum (2×109 CFU/g), daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo, daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golabchi Welfare Organization
Full name of responsible person
Reza Daneshvar
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
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
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Nutritionist
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Person responsible for updating data

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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