Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The effect of probiotic supplementation on cognitive, inflammation and oxidative stress in adults with Alzheimer disease: A randomized, double blind, placebo-controlled trial

Protocol summary

Study aim
Determining the effect of Lactobacillus rhamnosus HA-114 and Bifidobacterium longum R0175 probiotic supplements on cognitive function, inflammatory markers and oxidative stress in Alzheimer's patients

Design
Clinical trial, with a control and two intervention groups, parallel groups, double-blind, randomized, phase 3 on 90 patients, stratified permute block randomization in two classes based on (age and sex) using It will be done from www.randomization.com.

Settings and conduct
probiotic supplementation for 12 weeks will be performed on 3 groups of 30 people with Alzheimer's in neurology clinics of hospitals affiliated to Tehran University of Medical Sciences. . Supplements are coded by the company and researchers and participants are unaware of which supplement receives which group until the end of the analysis.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.Age 80-50 years 2.Resident of Tehran 3.Diagnosis of Alzheimer's disease 4.Kg/m2 30- 5/18 BMI= 5.Use of Alzheimer's drugs 6.consent of caregivers Criteria for non-entry: 1.Do not live in Tehran 2.Having dementia 3.Take antibiotics 4.Smoking 5.Any drug addiction 6.Follow a specific diet 7.Participate in another study 8.Take supplements or food products fortified with pre/ probiotics 9.History of serious disease 10.History of major gastrointestinal surgeries

Intervention groups
3 groups consisting of 30 Alzheimer's patients. The first group will receive 2 probiotic capsules containing 1 Lactobacillus rhamnosus HA-114 bacterial strain of CFU 1015 daily. Patients in the second group will receive 2 probiotic capsules containing 1 Bifidobacterium longum R0175 bacterial strain daily at the amount of CFU 1015 and the third group will receive 2 placebo capsules containing xylitol, maltodextrin and malic acid.

Main outcome variables
cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210513051277N1**
Registration date: **2021-05-27, 1400/03/06**
Registration timing: **prospective**

Last update: **2021-05-27, 1400/03/06**
Update count: **0**

Registration date
2021-05-27, 1400/03/06

Registrant information

Name
Camellia Akhgarjand

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 5975

Email address
kameliaakhgarjand@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotic supplementation on cognitive, inflammation and oxidative stress in adults with Alzheimer disease: A randomized, double blind, placebo-controlled trial

Public title
The effect of probiotic supplementation on cognitive function in Alzheimer's patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 80-50 years Resident of Tehran Diagnosis of Alzheimer's disease according to NINCDS-ARDA criteria maximum in the last 2 years BMI=18/5-30 Kg/m2 Use of acetylcholinesterase inhibitors (AchEIs) and N-methyl dispartate (NMDA) receptor antagonists caregivers understands the objectives of the study and agrees to follow the necessary rules throughout the study
Exclusion criteria:
Having frontotemporal dementia, Levy Buddy dementia, Parkinson's disease dementia and any type of severe dementia Take antibiotics at least three months before enrollment Smoking (at least 5 cigarettes a day for the past 6 months) and other tobacco (pipe and hookah at least once a month Any drug addiction Follow a specific diet for three months before the study People who participated in another study less than two months ago. Take any amount of supplements or foods fortified with fins or probiotics during the last 3 months History of serious kidney, liver, intestinal, endocrine diseases, cardiovascular, gastrointestinal, pulmonary, blood and metabolic diseases, thyroid, rheumatoid arthritis and lupus History of major gastrointestinal surgeries including gastrectomy, bowel restriction, etc.
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified permute block randomization will be performed in two categories based on (age and sex) using the site www.randomization.com. In this method, each group is assigned one of the letters A, B and C and randomization will be done in 6 blocks. This is done for both age groups and two lists are prepared based on age and gender. Within each class, patients will be randomly assigned to one of the three study groups in a 1: 1: 1 ratio.
Blinding (investigator's opinion)
Double blinded
Blinding description
All supplements will be provided by Lallemand Canada and are similar in color, taste and size. Supplements are coded by the company, and researchers, participants, data collectors and analysts, and the Data Safety and Supervision Committee are unaware of which group receives which supplement.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2021-05-15, 1400/02/25
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.152

Health conditions studied

1

Description of health condition studied
Alzheimer disease
ICD-10 code
G30
ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description

cognitive function

Timepoint

Measurement of cognitive function at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Mini–Mental State Examination questionnaire

Secondary outcomes

1

Description

serum level of IL-6

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Double Antibody Sandwich

2

Description

serum level of interleukin-10

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

enzyme-linked immunosorbent assay

3

Description

serum level 0f TNF-α

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Quantitative Sandwich

4

Description

serum level of 8-hydroxy-2' -deoxyguanosine (8-OHdG)

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Double Antibody Sandwich

5

Description

Serum levels of malondialdehyde (MDA)

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Colorimetric

6

Description

Serum level of glutathione

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Quantitative Sandwich

7

Description

Serum kynurenine levels

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Quantitative Sandwich

8

Description

Serum tryptophan levels

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Fluorometric

9

Description

Serum levels of lipopolysaccharide

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

quantitative sandwich enzyme immunoassay

10

Description

physical activity

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

questionnaire

11

Description

Quality of Life

Timepoint

at the beginning of the intervention (before the start of the intervention) and the end of week 12

Method of measurement

Quality of life in Alzheimer disease questionnaire (QOL-AD)

Intervention groups

1

Description

Intervention group: Patients in the first group will receive 2 probiotic capsules daily containing 1 bacterial strain of Lactobacillus rhamnosus HA-114 in the amount of CFU 1015. All supplements will be provided by Lallemand Canada and are similar in color, taste and size. Take 2 capsules daily, one after lunch and one after dinner. Supplements will be delivered to patients in two stages (study start and week 6).

Category

Other

2

Description

Intervention group: Patients in the second group will receive 2 probiotic capsules daily containing 1 bacterial strain of Bifidobacterium longum R0175 in the amount of CFU 1015. All supplements will be provided by Lallemand Canada and are similar in color, taste and size. Take 2 capsules daily, one after lunch and one after dinner. Supplements will be delivered to patients in two stages (study start and week 6).

Category

Other

3

Description

Control group: Patients in the intervention group will receive 2 placebo capsules daily containing xylitol, maltodextrin and malic acid. All supplements will be provided by Lallemand Canada and are similar in color, taste and size. Take 2 capsules daily, one after lunch and one after dinner. Supplements will be delivered to patients in two stages (study start and week 6).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Camellia Akhgarjand

Street address
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Tehran

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Tehran

Postal code
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Phone
+98 21 6693 9009

Email
Imamhospital@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraeian

Street address
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1417653911

Phone
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Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Camellia Akhgarjand

Position
PhD student

Latest degree
Master

Other areas of specialty/work
Nutrition

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1417653911

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kameliaakhgarjand@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kurosh Djafarian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Camellia Akhgarjand

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Nutrition

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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