

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of oral probiotic supplements on cognitive status, activity of daily living (ADL) and metabolic index in demented elderly: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Determining the effect of oral probiotic supplements on cognitive status, activity of daily living (ADL) and metabolic index in demented elderly

Design

Clinical trials with control group, with parallel groups, blind, randomized Sample size: 68 people (34 people per group)

Settings and conduct

The study is a double-blind randomized clinical trial that evaluates the effect of probiotic supplementation on cognitive status, activities of daily living and metabolic parameters in demented elderly patients during a period of 12 weeks. All patients aged 60 and older with dementia in mild or moderate stage, who refer to multidisciplinary clinic at Ziaeeian hospital in Tehran, enter into the study. A member of the research team who is blind about the content of capsules and the group of every individual, gives each patient 60 capsules monthly, up to 3 months

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged 60 and older, with dementia in mild or moderate stage who evaluated based on "(NIA-AA) 2011 Exclusive Criteria: 1. Chronic infections 2. Consumption probiotics 3. Taking antibiotics 4. severe gastrointestinal diseases 5. Alcohol consumption 6. severe heart disease, severe renal or liver impairment 7. Patients with frontotemporal dementia (FTD), dementia with Lewy bodies (DLB), Parkinson's disease dementia (PDD) and any demented patients in severe stage 8. Unwillingness to continue 9. Occurrence of delirium, stroke, prolonged hospitalization or inactivity and any diseases that affect cognitive or physical function

Intervention groups

The intervention group received oral probiotic supplements and the control group received placebo

randomly.

Main outcome variables

Mini Mental State Examination (MMSE): Functional assessment staging (FAST): Barthel Index: TG, Total Chol, HDL, LDL, FBS, Alb, Vit D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191008045024N1**
Registration date: **2019-12-28, 1398/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

Shima Raeesi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral probiotic supplements on cognitive status, activity of daily living (ADL) and metabolic index in demented elderly: A randomized, double-blind, placebo-controlled trial

Public title

Effect of Probiotics Supplementation on Cognitive Status, Daily Life Function and Metabolic Indexes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients aged 60 and older According to the 2011NIA-AA criteria for dementia in the mild to moderate stage
Obtaining informed consent

Exclusion criteria:

Chronic infections Consumption any products that contain probiotics or prebiotics during the recent 6 months Taking any kind of antibiotics during the month before starting the study History of any severe gastrointestinal diseases including celiac disease, inflammatory bowel diseases and diverticulitis or gastrointestinal surgery Alcohol consumption during 1 month before Suffering from severe heart disease, severe renal or liver impairment Patients with frontotemporal dementia (FTD), dementia with Lewy bodies (DLB), Parkinson's disease dementia (PDD) and any demented patients in severe stage, are also excluded because of their different nature and progression manner Occurrence of delirium at the beginning of the study

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups, case and control groups, using permuted block randomization. We use the website <http://www.sealedenvelope.com> for creation a random sequence in block randomization approach. It also advocates at specific sure to hide the allocation concealment. A number (specific code) is defined for each drug box according to the random sequence

created. Based on the order of participant's entrance to the study and the random number, each patient is divided into case or control group and receives probiotics supplementation or placebo, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

A member of the research team who is blind about the content of capsules and the group of every individual, gives each patient 60 capsules monthly, up to 3 months. Participants are requested to take two capsules each day. Patients in intervention group receive probiotic containing capsules and in control group, they receive placebo, which are exactly similar in appearance (including shape, size and color) and indistinguishable from probiotic containing capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee on Biomedical Research of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods Corner, Keshavarz Blvd.

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Province

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Postal code

1366736511

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.132

Health conditions studied**1****Description of health condition studied**

Dementia

ICD-10 code

F01

ICD-10 code description

Vascular dementia

2**Description of health condition studied**

Alzheimer's disease
ICD-10 code
G30
ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description

Mini Mental State Examination

Timepoint

The beginning of the study - 3 months later

Method of measurement

Mini Mental State Examination (MMSE) test

2

Description

Functional assessment staging

Timepoint

The beginning of the study - 3 months later

Method of measurement

Functional assessment staging test (FAST): Barthel Index

3

Description

Metabolic status

Timepoint

The beginning of the study - 3 months later

Method of measurement

Chek Serum TG, Total Chol, HDL,LDL, FBS, Alb, Vit D

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 68 patients receive 60 probiotic capsules (2 capsules daily for one month) and this continues for three months. Each probiotic capsule contains 500 mg and contains seven beneficial bacterial strains. The probiotic supplement is manufactured by "Zist Takhmir pharmaceutical company" in Tehran, Iran.

Category

Treatment - Drugs

2

Description

Intervention group: 68 patients receive 60 placebo capsules (2 capsules daily for one month) and this continues for three months. Each placebo capsule is similar to the probiotic capsule in Shape, size and color. The placebo is manufactured by "Zist Takhmir pharmaceutical company" in Tehran, Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaeian Hospital

Full name of responsible person

Shima Raeesi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Shima Raeesi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Geriatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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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