Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Ziaeian 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 infections2.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 stage8.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.
City
Tehran
Province
Tehran
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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Ziaeian Hospital, Aboozar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

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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
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Person responsible for scientific inquiries

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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