

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

Effect of probiotic supplementation on cognitive function and BDNF in patients with type 2 diabetes

Protocol summary

Study aim

The effect of probiotics supplementation on cognitive function and BDNF in patients with type 2 diabetes

Design

double blind randomized controlled trial

Settings and conduct

84 patients with type 2 diabetes 45-65 years old referred to Rasoul Akram Hospital and randomly assigned to either intervention or placebo groups (8 weeks). To measure fasting blood sugar, hemoglobin A1C, and serum BDNF, 10 ml of venous blood was collected after 10-12 hours of fasting at the beginning and end of the study. It will also be conducted to assess the cognitive performance of ACE and TMT cognitive tests at the end and end of the intervention.

Participants/Inclusion and exclusion criteria

1. Willingness to cooperate and complete informed consent Type 2 diabetes according to the diagnosis of a specialist based on patient records 3. At least 2 years of history of type 2 diabetes 4. No change in the type and dose of medication taken 8 weeks before the intervention 5- Age 45-65 6. No use of probiotic-containing foods for the past 4 weeks 1- Cancer, severe liver and kidney disorders, heart failure and surgery and other endocrine disorders 2-Pregnancy and lactation and hormone-sensitive conditions 3. Use of liver-degrading, anticoagulant, and platelet-derived drugs 4- Use of antidepressants and other drugs that affect the nerves 5. Insulin injection 6- Pregnancy Pills 7. Recent dietary supplements (no case of taking calcium, vitamin D and group B routinely for the past 6 months) 8- Use of antibiotics for the past 1 month 9- Tobacco, drugs and alcohol

Intervention groups

Intervention group: 2 capsules of 500 mg Foam Locket daily Control group: 2 capsules daily 500 mg placebo

Main outcome variables

cognitive function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090901002394N44**

Registration date: **2019-11-25, 1398/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-25, 1398/09/04**

Update count: **0**

Registration date

2019-11-25, 1398/09/04

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4805

Email address

sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic supplementation on cognitive function and BDNF in patients with type 2 diabetes

Public title

Effect of probiotic supplementation in patients with type 2 diabetes

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Willing to participate and signing informed consent
Having type 2 diabetes based on medical records
At least 2 years history of type 2 diabetes
No change in the type and dose of medication taken 8 weeks before the intervention
Age 45-65
Not eating probiotic-containing foods for the past 4 weeks

Exclusion criteria:

Cancer, severe liver and kidney disorders, heart failure and surgery and other endocrine disorders
Pregnancy and lactation and hormone-sensitive conditions
Use of liver, anticoagulant, and platelet-degrading drugs
Use of antidepressants and other drugs that affect the nerves
Insulin injection
Contraceptive use
Recent dietary supplements (no case if calcium - vitamin D and group B supplements are routinely consumed for the past 6 months)
Use of antibiotics for the past 1 month
Tobacco, drugs and alcohol weight loss diet and weight changes over 5% in the last 3 months

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects will be divided into two groups using block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double-blind the study of total cans containing capsules by a person other than the researcher, the researcher and statistical consultant and physician will be unaware of this classification. These divisions are based on random number tables

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Iran University of Medical Sciences

Street address

Shahid Hemmat Highway, next to Milad Hospital, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.IUMS.REC.1398.316

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

diabetes (mellitus)(nonobese)(obese): adult-onset
maturity-onset nonketotic stable non-insulin-dependent diabetes of the young

Primary outcomes

1

Description

cognitive function

Timepoint

at baseline, and after 2 month

Method of measurement

Addenbrooke's Cognitive Examination - Trail Making Test

2

Description

BDNF

Timepoint

at baseline, and after 2 month

Method of measurement

Eliza

Secondary outcomes

1

Description

physical activity

Timepoint

beginning and end of intervention

Method of measurement

IPAQ questionnaire

2

Description

energy intake

Timepoint

beginning and end of intervention

Method of measurement

Three-day food record

Intervention groups

1

Description

Intervention group: 2 capsules of 500mg familact daily for 12 weeks

Category

Treatment - Other

2

Description

Control group: Take 2 placebo capsules daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

hazraterasul hospital

Full name of responsible person

Dr amir ziyae

Street address

Hemmat Highway next to Milad Tower

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Jazayeri.sh@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Abbas Motevallian

Street address

تهران، بزرگراه همت، دانشگاه علوم پزشکی ایران

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motevalian@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

simakheradmand

Position

Master student in nutrition sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

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Phone

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr shima jazayeri

Position

Associate 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

Iran University of Medical Sciences

Full name of responsible person

simakheradmand

Position

Master student in nutrition sciences

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not 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

Yes - There is 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

Title and more details about the data/document

There is no more information

When the data will become available and for how long

There is no more information

To whom data/document is available

There is no more information

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable

There is no more information

What processes are involved for a request to access data/document

There is no more information

Comments