Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 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
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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-onsetmaturity-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 ziyaee
Street address
Hemmat Highway next to Milad Tower
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr Abbas Motevallian
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تهران،بزرگراه همت، دانشگاه علوم پزشکی ایران
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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
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
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simakheradmand
Position
Master student in nutrition sciences
Latest degree
Bachelor
Other areas of specialty/work
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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