Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation the effect of Probiotic supplement vs Placebo on anthropometric indices, quality of life, body composition, blood pressure, lipid profile and serum levels of adipokines and atherosclerosis dependent indices in elderlies with type 2 diabetes and high cardiovascular risk

Protocol summary

Study aim

To determine the effect of Probiotic supplement vs Placebo on anthropometric indices, quality of life, body composition, blood pressure, lipid profile, and serum levels of adipokines and atherosclerosis dependent indices in elderly with type 2 diabetes and high cardiovascular risk

Design

A controlled, randomized, triple-blinded, clinical trial with a parallel-group design

Settings and conduct

A single-center clinical trial in the elderlies with type 2 diabetes

Participants/Inclusion and exclusion criteria

Inclusion criteria: > 65 years old, diagnosed as having T2DM, at least moderately controlled diabetes, a stable anti-diabetic drug regimen before starting the study, and high risk for cardiovascular events Exclusion criteria: Consumption of other Probiotic supplements and food products during the study, multivitamin-mineral supplements or medicinal products that interfere with patients' anthropometric indices, blood pressure, lipid profile, and serum levels of adipokines and atherosclerosis dependent indices, cancer, and any chronic disease other than diabetes, smoking, drinking, uncontrolled blood pressure, acute gastrointestinal problem, consumption of antibiotics during the study and unusual stressful event during the study

Intervention groups

Intervention group: Multistrain Probiotics Capsule, containing Lactobacillus rhamnosus, Helveticus, casei, acidophilus, bulgaricus, plantarum and Gasseri and Bifidobacterium lactis, Breve, Langum and bifidum and Streptococcus thermophilus with CFU 109 Manufactured by Zist Takhmir Co. one capsule daily for 4 months Control group: placebo capsule in completely similar design, color, smell, taste and shape to probiotic capsule and without microorganisms, Manufactured by Zist Takhmir Co. one capsule daily for 4 months

Main outcome variables

Changes in anthropometric indices and serum levels of adipokines and serum atherosclerosis associated indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N6**
Registration date: **2021-01-25, 1399/11/06**
Registration timing: **prospective**

Last update: **2021-01-25, 1399/11/06**
Update count: **0**

Registration date

2021-01-25, 1399/11/06

Registrant information

Name
Neda Dolatkhah
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3336 1928
Email address
dolatkhahn@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2022-03-21, 1401/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of Probiotic supplement vs Placebo on anthropometric indices, quality of life, body composition, blood pressure, lipid profile and serum levels of adipokines and atherosclerosis dependent indices in elderlies with type 2 diabetes and high cardiovascular risk

Public title
Probiotic supplement in elderlies with type 2 diabetes and high cardiovascular risk
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
> 65 years old Diagnosed as having T2DM based on the criterion of the American Diabetes Association At least moderately controlled diabetes (HbA1c<8.5%) A stable anti-diabetic drug regimen (over 4 months) before starting the study Body mass index <45 kg/m2 High risk of cardiovascular events: Albuminuria in two of three random urine samples in the last 24 hours and a positive history of macrovascular events
Exclusion criteria:
Consumption of other Probiotic supplements and food products during the study Multivitamin-mineral supplements or medicinal products that interfere with patients' anthropometric indices, blood pressure, lipid profile, and serum levels of adipokines and atherosclerosis dependent indices Cancer and any chronic disease other than diabetes Smoking Drinking Uncontrolled blood pressure Uncontrolled severe diabetes Acute gastrointestinal problem Consumption of antibiotics during the study Unusual stressful event during the study
Age
From **65 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: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
A block randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS) with block sizes of 2and 4. Similarly sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package
Blinding (investigator's opinion)
Triple blinded
Blinding description
Probiotic and placebo supplements will be prepared in exactly the same way in terms of shape, color and odor, and will be placed in a small envelope containing 30 to 31 capsules for each participant for monthly consumption. The envelopes will be opened in the order in which the participants enter this stage from number 1, and an envelope containing the supplement will be provided to the participant for one month. Outcome assessors, the person responsible for statistical analysis of the data, and the respondents will be blinded to the type of supplement received until the end of the study
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
3654895785
Approval date
2020-12-28, 1399/10/08
Ethics committee reference number
IR.TBZMED.REC.1399.917

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

5A11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Weight

Timepoint

Measurement of the weight at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

SECA digital scale

2

Description

Body mass index

Timepoint

Measurement of the body mass index at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Calculation (division of weight in kilograms by height squared in meters)

3

Description

Resistin

Timepoint

Measurement of the Resistin at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

4

Description

Chemerin

Timepoint

Measurement of the Chemerin at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

5

Description

Vascular cell adhesion molecule (VCAM)-1

Timepoint

Measurement of the Vascular cell adhesion molecule (VCAM)-1 at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

6

Description

Intercellular adhesion molecule (ICAM)-1

Timepoint

Measurement of the Intercellular adhesion molecule (ICAM)-1at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

7

Description

E-selectins

Timepoint

Measurement of the E-selectins at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

Secondary outcomes

1

Description

Quality of life

Timepoint

Evaluation of the quality of life at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

LEIPAD quality of life questionnaire

2

Description

Blood pressure

Timepoint

Measurement of the blood pressure at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Mercury barometer

3

Description

Blood Triglyceride

Timepoint

Measurement of the blood Triglyceride at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

4

Description

Blood total Cholesterol

Timepoint

Measurement of the blood total Cholesterol at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

5

Description

Blood LDL Cholesterol

Timepoint

Measurement of the blood LDL Cholesterol at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

6

Description

Blood HDL Cholesterol

Timepoint

Measurement of the blood HDL Cholesterol at the beginning of the study (before the intervention) and 4 months after the start of Probiotic supplementation

Method of measurement

Biochemical analysis

Intervention groups

1

Description

Intervention group: The multi strain Probiotic capsule containing Lactobacillus rhamnosus, Lactobacillus Helveticus, Lactobacillus casei, Bifidobacterium lactis, Lactobacillus acidophilus, Bifidobacterium Breve, Lactobacillus bulgaricus, Bifidobacterium Langum, Lactobacillus plantarum, Bifidobacterium bifidum, Lactobacillus Gacery and Streptococcus thermophilus to the CFU 109 manufactured bt Zist Takhmir Co. once daily for 4 months

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule with completely similar appearance characteristics including shape, color, smell and taste to probiotic capsule without microorganisms manufactured bt Zist Takhmir Co. once daily for 4 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Neda Dolatkhah

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Phone

+98 41 3336 1928

Email

neda_dolatkhah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5986365489

Phone

+98 41 3334 4280

Fax

+98 41 3334 4280

Email

Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkhah
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Emam Reza hospital, Golgasht Str., Azadi Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5163995479
Phone
+98 41 3336 1928
Email
neda_dolatkhah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkhah
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Emam Reza hospital, Golgasht Str., Azadi Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5163995479
Phone
+98 41 3336 1928
Email
neda_dolatkhah@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkhah
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Emam Reza hospital, Golgasht Str., Azadi Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
5163995479
Phone
+98 41 3336 1928
Email
neda_dolatkhah@yahoo.com

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