Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effects of synbiotic supplement on microbiome, TNFa and expression of microRNA-126, microRNA-146a in T2DM patients

Protocol summary

Study aim
Study of the effect of synbiotic supplementation on gut microbial, TNF-a and expression of mirRNA-126 and mirRNA-146a in patients with type 2 diabetes

Design
A clinical trial with a control group, with parallel, double-blind, and randomized groups, will be performed on patients with type 2 diabetes. 72 patients will be randomly assigned to receive the synbiotic and the placebo by using a random number table.

Settings and conduct
The study is designed as a double blind randomized controlled trial. After receiving informed consent, the demographic information questionnaire will be completed. At the beginning and end of the study,Biochemical and anthropometric measurements and body composition are performed, diet and physical activity will be evaluated by the three-day record form, Expression of microRNA-126 and microRNA-146a will be measured by RealTime PCR, and serum levels of TNF-a will be measured by ELISA and determination of gut microbiom in participants stool samples will be performed with the use of QPCR.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men and women with type 2 diabetes, In the age range of 25-65 years, Glycosylated hemoglobin above 6.5% and below 8.5%, BMI 25-35. Exclusion criteria: People with low-immune, pregnant and lactating women, people with special diseases and allergies, inflammatory diseases, and those who use hormone replacement therapy, probiotic consumption or antibiotic treatment within the past month.

Intervention groups
The intervention group will receive synbiotic capsules (containing probiotic, fructo-oligosaccharide as prebiotic, lactose, magnesium stearate, talc) containing 500 mg and the control group will receive placebo (lactose, magnesium stearate, talc) containing 500 mg for 12 weeks twice a day.

Main outcome variables
Expression of microRNA-126 and microRNA-146a, serum levels of TNF-a, gut microbiom(6 microorganism)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180624040228N2**
Registration date: **2019-03-27, 1398/01/07**
Registration timing: **prospective**

Last update: **2019-09-25, 1398/07/03**
Update count: **1**

Registration date
2019-03-27, 1398/01/07

Registrant information
Name
Fahime Zeinali
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3820 9143
Email address
fghzeinaly@ssu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-20, 1398/01/31
Expected recruitment end date
2020-03-19, 1398/12/29
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of synbiotic supplement on microbiome, TNFa and expression of microRNA-126, microRNA-146a in T2DM patients

Public title

Synbiotic and gut microbiome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women with type 2 diabetes (the minimum elapsed time of diagnosis is 3 months and diabetes treatment is started in person) Age range 25 to 65 years Glycosylated hemoglobin above 6.5% and below 8.5% BMI is between 25 and 35

Exclusion criteria:

Using alternative therapies with hormone (Insulin, Corticosteroids) or vitamin supplements Chronic kidney, liver, pulmonary diseases. chronic or acute inflammatory diseases (especially acute Pancreatic inflammation and Endocarditis)Valvular disease of the heart. Irritable Bowel Syndrome. Allergic Diabetes complications (Nephropathy, Cardiomyopathy, Retinopathy, Diabetic foot ulcers) People with low immune system (Autoimmune)Pregnancy, Lactation Use of tobacco and alcohol Probiotic consumption or treatment with antibiotics within the past month Follow the unusual diet up to 1month before the study

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

To assign individuals to the intervention and control groups, a random number table will be used. Stratified blocked randomization method will be used based on sex (male and female) and age (25-45 years and 45-65 years), so that the number of samples assigned to each of the groups will be equal.

Blinding (investigator's opinion)

Double blinded

Blinding description

Capsules containing synthetic and placebo are similar in shape and appearance and the bottles of Capsules are the same (in terms of color and shape). A and B labels will be fixed on the bottles of Capsules by someone irrelevant to the entire study. participants and researchers will be blinded to the contents in the bottles through out the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Health Faculty, Shahid Sadoughi University of Medical Sciences, Shohadaye gomnam Blvd, Alam Sqrt

City

yazd

Province

Yazd

Postal code

8915173160

Approval date

2019-03-08, 1397/12/17

Ethics committee reference number

IR.SSU.REC.1397.179

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

gut microbiom

Timepoint

Before and immediately after the intervention

Method of measurement

Quantitative Real time Polymerase Chain Reaction (QPCR) and 16s rRNA sequencing

2

Description

Expression of microRNA-126

Timepoint

Before and immediately after the intervention

Method of measurement

Real time Polymerase Chain Reaction (PCR)

3

Description

Experation of microRNA-146a

Timepoint

Before and immediately after the intervention

Method of measurement

Real time Polymerase Chain Reaction (PCR)

4

Description

Serum levels of tumor necrosis factor alpha

Timepoint

Before and immediately after the intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Triglyceride

Timepoint

Before and immediately after the intervention

Method of measurement

Turbidity test

2

Description

Total cholesterol

Timepoint

Before and immediately after the intervention

Method of measurement

Turbidity test

3

Description

High-density lipoprotein

Timepoint

Before and immediately after the intervention

Method of measurement

Turbidity test

4

Description

Low-density lipoprotein

Timepoint

Before and immediately after the intervention

Method of measurement

Turbidity test

5

Description

Fasting Blood Sugar

Timepoint

Before and immediately after the intervention

Method of measurement

Turbidity test

6

Description

Glycosylated hemoglobin

Timepoint

Before and immediately after the intervention

Method of measurement

Enzymatic Assay Kit

7

Description

fasting insulin

Timepoint

Before and immediately after the intervention

Method of measurement

ELISA kit

Intervention groups

1

Description

Intervention group: Intervention group: The intervention group will receive synbiotic capsules (containing probiotic, fructo-oligosaccharide as prebiotic, lactose, magnesium stearate, talc) containing 500 mg for 12 weeks twice a day.

Category

Prevention

2

Description

Control group: The control group will receive placebo (lactose, magnesium stearate, talc) containing 500 mg for 12 weeks twice a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Fahime Zeinali

Street address

Yazd Diabetes Research Center, Shahid Sadoughi Blvd

City

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Postal code
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Phone
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Email
drc@ssu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Diabetes Research Center
Full name of responsible person
Fahime Zeinali
Street address
Yazd Diabetes Research Center, Shahid Sadoughi Blvd
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3728 0228
Email
drc@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd Diabetes Research Center
Proportion provided by this source
30
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
Other

2

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fahime Zeinali
Street address
Health Faculty, Shahid Sadoughi University of Medical Sciences, Shohadaye gomnam Blvd, Alam Sqrt
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Postal code
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Phone
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Email
fghzeinaly@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
70
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
Yazd Diabetes Research Center
Full name of responsible person
Fahime Zeinali
Position
student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
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Email
fghzeinaly@ssu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Hassan Mozaffari-Khosravi
Position

Professor (Full)

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Health Faculty, Shahid Sadoughi University of Medical Sciences, Shohadaye gomnam Blvd, Alam Sqrt
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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fahime Zeinali

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Health Faculty, Shahid Sadoughi University of Medical Sciences, Shohadaye gomnam Blvd, Alam Sqrt
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Email

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable