

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Study of the effect of synbiotic supplement on glycemic and lipid profile indices, inflammatory factors, oxidative stress condition and expression of related microRNAs in T2DM patients

#### Protocol summary

##### Study aim

Study of the effect of synbiotic supplement on glycemic and lipid profile indices, inflammatory factors, oxidative stress condition and expression of microRNA-126, microRNA-146a in T2DM patients

##### 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 using standard methods, diet and physical activity will be evaluated by the three-day food record form and the three-day physical activity record form, Expression of microRNA-126 and microRNA-146a will be measured by RealTime PCR, and serum levels of IL6, TNF-a, MDA, and TAC will be measured by ELISA.

##### 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, and people who use alcohol and tobacco.

##### 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 IL6, TNF-a, MDA, and TAC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180624040228N1**

Registration date: **2018-07-21, 1397/04/30**

Registration timing: **prospective**

Last update: **2019-03-19, 1397/12/28**

Update count: **1**

##### Registration date

2018-07-21, 1397/04/30

##### 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

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-03-19, 1397/12/28

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Study of the effect of synbiotic supplement on glycemic and lipid profile indices, inflammatory factors, oxidative stress condition and expression of related microRNAs in T2DM patients

**Public title**  
synbiotic in diabetes

**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 in the last three months 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**

2018-03-16, 1396/12/25

##### **Ethics committee reference number**

IR.SSU.SPH.REC.1396.172

### **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**

Expression of microRNA-126

##### **Timepoint**

Before and immediately after the intervention

##### **Method of measurement**

Real time Polymerase Chain Reaction (PCR)

## 2

### **Description**

Experation of microRNA-146a

### **Timepoint**

Before and immediately after the intervention

### **Method of measurement**

Real time Polymerase Chain Reaction (PCR)

## 3

### **Description**

Serum levels of interleukin 6

### **Timepoint**

Before and immediately after the intervention

### **Method of measurement**

ELISA kit

## 4

### **Description**

Serum levels of tumor necrosis factor alpha

### **Timepoint**

Before and immediately after the intervention

### **Method of measurement**

ELISA kit

## 5

### **Description**

Serum levels of Malondialdehyde

### **Timepoint**

Before and immediately after the intervention

### **Method of measurement**

ELISA kit

## 6

### **Description**

Serum levels of total antioxidant capacity

### **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: 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

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drc@ssu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Research Deputy of Health Faculty

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

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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

**2**

**Sponsor**

**Name of organization / entity**

Iran National Science Foundation

**Full name of responsible person**

Zargham Nosratollah

**Street address**

No. 33, 5th street, North Kargar

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Tehran

**Province**

Tehran

**Postal code**

1439634665

**Phone**

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**Email**

medicine@insf.org

**Grant name**

**Grant code / Reference number**

96012141

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

Yes

**Title of funding source**

Iran National Science Foundation

**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

**Person responsible for general inquiries**

**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

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## 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

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## Person responsible for updating data

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Yazd University of Medical Sciences

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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**

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

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable