

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of probiotic on control of glucose and lipid index in pre-diabetic patients

#### Protocol summary

##### Study aim

Pre-diabetic patients are referred for metabolic disorders more and more. Since medical treatment is still suspected in these patients, the aim of this study is to compare the control of sugar and lipid by diet and lifestyle modification alone against these methods as well as probiotic intake. Many researchers believe, probiotic consumption change the sugar homeostasis and improve the type 2 diabetes.

##### Design

Two arm parallel group randomized trial with blinded postoperative controlled trial

##### Settings and conduct

In the office, we provide the conditions that both the patient and the doctor and the assessor are unaware of the type of card and treatment received.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All diabetic patients aged 30 to 65 years with each of the following criterias: 1.Fasting blood sugar between 100 and 125 2. Blood glucose 2 hours after food between 140 and 199 3. Blood glucose 2 hours after eating 75 g of glucose from 140 to 199 4- HBA1C Between 5.7% and 6.4% Exclusion Criterias: Patients with previous diagnosis of diabetes Patients with pre-diabetic diagnosis that are under medical treatment GFR <60 A history of known digestive malformations or chronic diarrhea Receive probiotics, antibiotics, aspirin or B vitamins during the last three months

##### Intervention groups

In treatment group, 500 mg probiotic capsule per day for three months, and in the other group, the capsule is given as placebo.

##### Main outcome variables

Fasting blood sugar; HbA1c

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180527039866N1**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

#### Registration date

2018-08-02, 1397/05/11

#### Registrant information

##### Name

Somayeh sadat Shariatmaghani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3845 8779

##### Email address

shariatmaghanis@mums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-07-23, 1397/05/01

#### Expected recruitment end date

2019-01-21, 1397/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of probiotic on control of glucose and lipid index in pre-diabetic patients

#### Public title

The effect of probiotics in the treatment of prediabetic

## **Purpose**

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

All pre diabetic patients 30 to 65 years old

### **Exclusion criteria:**

Patients with previous diagnosis of diabetes Pre-diabetic patients that are under medical treatment GFR<60 A history of known digestive malformations or chronic diarrhea Receive probiotics, antibiotics, aspirin or B vitamins during the last three months

## **Age**

From **30 years** old to **65 years** old

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **70**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Patients are randomly divided into two groups, one group being treated with probiotic pills and another group being treated with placebo. The method of randomization is that two cards are prepared and numerical coding 1 and 2 are recorded on it. Group 1 is related to probiotics and group 2 to placebo. Each patient is drawn with one of the cards without inserting the cards. We provide the conditions that both the patient and the doctor are unaware of the type of card and the treatment received, and blindness will occur.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

All participants in the study are unaware of the use of placebo or probiotics. They are grouped into a group based on the drawing of the card and provided with explanations that they may be in groups 1 and 2. The program Food, exercise, and how to use medication or placebo for everyone is the same. Care provider does not know that each participant is in which groups. Randomization is done by another one, outside the clinic room. The investigator or outcome assessor is also unaware of the status of the participants. Participants are referred to care provider after the randomization, and the questionnaire and the necessary explanations for the plan are given to them. Data analyser also does not contact the participants and does not know which group 1 and 2 are taking placebo or medication.

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Science

##### **Street address**

Daneshgah Street.,in front of 18 Ave.,Mashhad University of Medical Science

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9138735499

#### **Approval date**

2017-11-01, 1396/08/10

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

IR.MUMS.fm.REC.1396.451

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Prediabetes

#### **ICD-10 code**

R73.0

#### **ICD-10 code description**

Abnormal glucose tolerance test

## **Primary outcomes**

### 1

#### **Description**

Fasting Blood sugar

#### **Timepoint**

Before the intervention and three months after the intervention began

#### **Method of measurement**

Blood sampling

### 2

#### **Description**

HbA1c

#### **Timepoint**

Before the intervention and three months after the intervention began

#### **Method of measurement**

Blood sampling

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Pre-diabetes patients with a standard definition, are treated with probiotic capsule is given at a rate of more than 10<sup>9</sup> CFUs equivalent to 500 mg of capsules, daily. The lactacactor contains lactate and lactobacillus acidophilus.

### Category

Treatment - Drugs

2

### Description

Control group: Pre-diabetes patients with a standard definition are are treated with placebo daily.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ghaem hospital

#### Full name of responsible person

Somayehsadat Shariatmaghani

#### Street address

Gaem hospital.,Ahmadabad street.,Doctor shariati square.,Mashhad

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9176999311

#### Phone

+98 51 3840 0000

#### Email

quaem@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi, Deputy of Research and Technology of Mashhad University of Medical Sciences

#### Street address

Daneshgah Street.,in front of 18 Ave.,Mashhad  
Univercity of Medical Science

### City

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### Province

Razavi Khorasan

### Postal code

91735951

### Phone

+98 51 3841 1538

### Fax

+98 51 3843 0249

### Email

vcresearch@mums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Somayeh sadat Shariatmaghani

#### Position

Assotiated professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

No 9,Rahnamaii Ave 13,Rahnamaii street.,Mashhad

#### City

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#### Province

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#### Postal code

1475815944

#### Phone

+98 51 3845 8779

#### Fax

#### Email

shariatmaghanis@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Somayeh sadat Shariatmaghani

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Assotiated professor

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information on the main consequence of participants' data after being unidentifiable is shared If authorized by Mashhad University of Medical Sciences.

**When the data will become available and for how long**

Six months after printing results

**To whom data/document is available**

Researchers working in scientific institutions

**Under which criteria data/document could be used**

If the type of analysis is relevant to general health.

**From where data/document is obtainable**

By email address:MDS resaerch@mums.ac.ir

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

Contact with the vice chancellor for research at Mashhad University of Medical Sciences by email mentioned the above. If the university agrees, the information will be sent by email.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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