

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of probiotic yogurt consumption on glycemic control and lipid profile in patients with type 2 diabetes mellitus: A double-blind randomized controlled trial

#### Protocol summary

##### Study aim

Effect of probiotic yogurt consumption on glycemic control and lipid profile in patients with type 2 diabetes

##### Design

Sampling method: The initial selection of patients in this study is available and then will be randomly assigned to two groups: Based on the inclusion criteria and with the help of a random number table, an Excel list of 300 patients with a file is prepared. All study samples are explained about the objectives of the study and they are told that they will be included in one of the study groups (test or control). The studied samples are then asked to go to the diabetes clinic and complete the informed consent form to participate in the study. How to randomize: Using the RANDBETWEEN command in Excel software, 40 people are randomly assigned in the test group and 40 people in the control group.

##### Settings and conduct

All patients with diabetes who have been diagnosed with type 2 diabetes for at least six months and have a record in Yazd Diabetes Clinic will form the research community

##### Participants/Inclusion and exclusion criteria

All patients with diabetes who have been diagnosed with type 2 diabetes for at least six months and have a file in Yazd Diabetes Clinic will form a research community.

##### Intervention groups

Individuals in the experimental group received 200 g of probiotic yogurt containing Lactobacillus acidophilus and Bifidobacterium lactis daily, and individuals in the control group received 200 g of normal yogurt daily (lunch and dinner) for 3 months.

##### Main outcome variables

Blood sugar/Glycosylated A1C/Cholesterol LDL/HDL/Tri glyceride/

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220226054125N1**

Registration date: **2022-07-30, 1401/05/08**

Registration timing: **retrospective**

Last update: **2022-07-30, 1401/05/08**

Update count: **0**

##### Registration date

2022-07-30, 1401/05/08

##### Registrant information

##### Name

Ali salarisharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 1751

##### Email address

a.salarisharif@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-04, 1398/01/15

##### Expected recruitment end date

2020-12-20, 1399/09/30

##### Actual recruitment start date

2019-04-04, 1398/01/15

##### Actual recruitment end date

2020-12-20, 1399/09/30

##### Trial completion date

2021-06-20, 1400/03/30

**Scientific title**

Effect of probiotic yogurt consumption on glycemic control and lipid profile in patients with type 2 diabetes mellitus: A double-blind randomized controlled trial

**Public title**

Effect of probiotic yogurt consumption on glycemic control and lipid profile in patients with type 2 diabetes mellitus: A double-blind randomized controlled trial

**Purpose**

Screening

**Inclusion/Exclusion criteria****Inclusion criteria:**

The inclusion criteria included patients with T2DM low density lipoprotein-cholesterol (LDL-c) equal to or greater than 100 mg/dl age between 30-60 years taking metformin and Gli Banglamide tablets with correct gastrointestinal function according to patient not taking blood lipid lowering drugs

**Exclusion criteria:**

The inclusion criteria included patients with T2DM low density Lipoprotein-cholesterol (LDL-c) equal to or greater than 100 mg/dl age between 30-60 years taking metformin and Gli Banglamide tablets with correct gastrointestinal function according to patient not taking blood lipid lowering drugs

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The initial selection of patients in this study is available and will then be randomly assigned to two groups: Based on the inclusion criteria and with the help of a random number table, an Excel list of 300 patients with a file is prepared. The researchers will then establish a list of telephone contacts with the patients in order, and each patient who meets the inclusion and exclusion criteria will be included in the study. This will continue until the desired sample size (80 people) is reached. All study samples are explained about the objectives of the study and they are told that they will be included in one of the study groups (test or control). The studied samples are then asked to go to the diabetes clinic and complete the informed consent form to participate in the study. How to randomize: Using the RANDBETWEEN command in Excel software, 40 people are randomly assigned in the test group and 40 people in the control group.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

This study is designed as a three-way blind. In the first stage, the patient does not know in which group (test or control) he is. People who do blood sampling, not data analysts, do not know what group each person is in (test or control). In this three-blind randomized controlled clinical trial, 80 type 2 diabetic patients with high blood sugar above 100 mg / dL are divided into two groups. The experimental group received 200 g of probiotic yogurt containing Lactobacillus acidophilus and Bifidobacterium lactis daily and the control group received 200 g of normal yogurt daily (lunch and dinner) for 3 months. Anthropometric indices, blood glucose and serum lipid levels are measured at the beginning and end of the study.

**Placebo**

Used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

IR.SSU.REC

**Street address**

Yazd Diabetic Research Center, at the end of the Art hall alley, Bahnar Square towards Azadi Square, Shahid Sadoughi Blvd, Yazd,Iran

**City**

Yazd

**Province**

Yazd

**Postal code**

۸۹۱۷۶۹۳۵۷۱

**Approval date**

2014-11-26, 1393/09/05

**Ethics committee reference number**

IR.SSU.REC.1393.181431

**Health conditions studied****1****Description of health condition studied**

Effect of probiotic yogurt consumption on glycemic control and lipid profile in patients with type 2 diabetes mellitus

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

blood sugar

#### Timepoint

Before and after study

#### Method of measurement

Using Pars Azmoun commercial kits

### 2

#### Description

Hemoglobin A1c

#### Timepoint

Before and after study

#### Method of measurement

Using Pars Azmoun commercial kits

### 3

#### Description

cholesterol and Triglyceride

#### Timepoint

Before and after study

#### Method of measurement

By photometric method using Pars Azmoun commercial kits

### 4

#### Description

HDL

#### Timepoint

Before and after study

#### Method of measurement

By photometric method using Pars Azmoun commercial kits

### 5

#### Description

LDL

#### Timepoint

Before and after study

#### Method of measurement

By photometric method using Pars Azmoun commercial kits

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The subjects of the test group receive 200 grams of probiotic yogurt containing Lactobacillus acidophilus and Bifidobacterium lactis daily for three months.

#### Category

Treatment - Drugs

### 2

#### Description

People in the control group will receive 200 grams of regular yogurt daily (lunch and dinner) for 3 months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabetes Research Center affiliated with Shahid Sadoughi University of Medical Sciences, Yazd, Iran

##### Full name of responsible person

Ali Salari Sharif

##### Street address

Nursing and Midwifery Research Center Safaieh Bouali St.

##### City

Yazd

##### Province

Yazd

##### Postal code

8916877443

##### Phone

+98 35 3824 1755

##### Fax

+98 35 3824 9705

##### Email

Microb.5656@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Ali Salar Sharif

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Safaieh Bouali St. Nursing and Midwifery Research Center

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#### Grant name

Vice Chancellor for Research and Technology, Shahid

Sadoughi University of Medical Sciences, Yazd  
**Grant code / Reference number**  
3713  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Vice Chancellor for Research and Technology, Shahid Sadoughi University of Medical Sciences, Yazd  
**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**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Ali Salari Sharif  
**Position**  
Reasercher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Microbiology  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Ali Salarisharif  
**Position**  
Researcher  
**Latest degree**  
Master

### Other areas of specialty/work

Microbiology  
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School of Nursing and Midwifery, in front of Reproductive and Infertility Research Institute, Bouali Alley, Timsar Fallahi St, Safaieh, Yazd  
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## Person responsible for updating data

### Contact

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microb.5656@gmail.com  
**Web page address**

## 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

Due to the confidentiality of patients' personal information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not 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**

Personal information of the studied samples is unidentified

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

After publishing the article

**To whom data/document is available**

Access to the results after the publication of the article is possible for everyone

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

It is possible to use the data by requesting the following email [microb.5656@gmail.com](mailto:microb.5656@gmail.com)

**From where data/document is obtainable**

By sending a request to the email of the responsible author

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

After receiving the email, it will be answered within two weeks

**Comments**