

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.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

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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

Researcher

Latest degree

Master

Other areas of specialty/work

Microbiology

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Position

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Other areas of specialty/work

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Person responsible for updating data

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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

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