

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of probiotics supplementation on glycemic control and metabolic parameters in type 1 diabetic patients

Protocol summary

Study aim

Determining the effect of probiotic supplementation on glycemic control and metabolic parameters in type 1 diabetic patients

Design

Double-blind controlled randomized clinical trial, with parallel groups, using double blocks for randomization.

Settings and conduct

Sampling will be done in the Diabetes and Metabolic Patients Clinic of the Institute of Endocrinology and Metabolism in Tehran. Prior to the intervention, all selected individuals enter the Run-in period for two weeks. For randomization, the subjects were aged in terms of age, the number of units of injectable insulin (maximum 6 units difference), and duration of type 1 diabetes (maximum 3 years difference) will be placed in double blocks. The individuals in each block are then divided into intervention and comparison groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having type 1 diabetes (fasting blood sugar greater than 125 mg / dL and HbA1C greater than 6.5% if confirmed by an endocrinologist) Age over 7 and under 18 years At least one year after developing type 1 diabetes Non-inclusion criteria: Have liver, kidney, inflammatory, or immunodeficiency diseases Pregnancy or breastfeeding Taking antibiotics in the last two months Consume foods containing probiotics or probiotic supplements over the past month Tobacco use or drugs Take dietary supplements or non-steroid anti-inflammatory drugs for 1 month before the study

Intervention groups

Individuals in the probiotic supplement intervention group consisting of 6 strains of Lactobacillus, Bacillus coagulans, Bifidobacterium, and maltodextrin and the placebo group will receive one placebo, which contains maltodextrin and does not contain probiotic bacteria, one a day for 12 weeks.

Main outcome variables

HbA1C and FBS Serum levels of TG, total cholesterol,

LDL-C, and HDL-C Number of units of injectable insulin blood pressure Anthropometric indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201203049576N1**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **prospective**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

Saeedeh Nourimajd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2245 3368

Email address

snourimajd@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-03, 1399/10/14

Expected recruitment end date

2021-06-19, 1400/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics supplementation on glycemic control and metabolic parameters in type 1 diabetic patients

Public title

The effect of probiotics supplementation in type 1 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 1 diabetes (fasting blood sugar greater than 125 mg / dL and HbA1C greater than 6.5% if confirmed by an endocrinologist) Age over 7 and under 18 years At least one year after developing type 1 diabetes Willingness to participate in the study

Exclusion criteria:

Having liver, kidney, inflammatory, or immunodeficiency diseases Taking antibiotics over the last two months Consuming foods containing probiotics or probiotic supplements over the past month Taking dietary supplements or non-steroid anti-inflammatory drugs during 1 month before the study

Age

From **7 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization: Block randomization is intended to ensure that exactly the same number of participants enter the intervention and comparison groups at consecutive intervals. For this purpose, the subjects will be divided into double blocks in terms of age, the number of units of injection insulin (maximum 6 units difference), and duration of type 1 diabetes (maximum 3 years difference). Then the people in each block will be divided into intervention and comparison groups. In order to randomly assign individuals to groups, each person is given a code and these codes are poured into a pot. An out-of-study person is then asked to draw the codes out of the pot using a lottery. The first code of each block will be assigned to the intervention group, the second code will be assigned to the comparison group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants, researchers, and physicians do

not know the type of intervention of placebo capsules or probiotic capsules. In this regard, one code is assigned to the placebo capsule and one code to the probiotic capsule, which is reserved by the manufacturer, and at the end of the study, the intervention and comparison groups will be identified. In this way, two people who are in a block will be given two types of capsules with different codes. Each person will be given capsules with one code and that code will be written first. After the study, the relevant person in charge of the company will be contacted and the code related to the placebo capsules and the code related to the probiotic capsules will be asked and the members of the intervention and comparison group will be identified. Placebo capsules will be no different from supplement capsules in shape, smell, color, and taste.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

No. 44, Hojjatdoost Alley, Naderi St, Keshavarz Boulevard, Tehran University of Medical Sciences and Health Services, Faculty of Nutrition and Dietetics

City

Tehran

Province

Tehran

Postal code

1416643931

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.827

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

Type 1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Hemoglobin A1c (HbA1C)

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

Enzymatically using commercial kits

2

Description

Fasting blood sugar level (FBS)

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

By glucose oxidase method and using commercial kits

3

Description

Serum triglyceride levels (TG)

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

Using glycerol phosphate oxidase and commercial kits

4

Description

Serum high-density lipoprotein cholesterol level (HDL-C)

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

HDL-C concentration after deposition of lipoproteins with apo lipoprotein B

5

Description

Total cholesterol

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

By cholesterol oxidase and cholesterol esterase methods and using commercial kits

6

Description

Serum low-density lipoprotein cholesterol level (LDL-C)

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

Using the Friedewald formula

7

Description

Number of units of injection insulin

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

Questions and registrations

8

Description

Blood pressure

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

Sphygmomanometer

9

Description

Anthropometric indicators

Timepoint

At the beginning of the study and at the end of the study (after 12 weeks)

Method of measurement

Meters, scales

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive a probiotic supplement capsule. This supplement will be produced by the tak gene zist company, which consists of 6 bacterial strains including Lactobacillus acidophilus, Lactobacillus casei, Bacillus coagulans, Bifidobacterium lactis, Bifidobacterium longum, Bifidobacterium Bifidiom [3 × 10⁹ (CFU / gr)] and maltodextrin. This supplement should be taken daily by participants for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: This group will take the placebo capsule, which contains maltodextrin and does not contain probiotic bacteria, daily for 12 weeks. This capsule will be produced by the tak gene zist company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes and Metabolic Patients Clinic of the Institute of Endocrinology and Metabolism in Tehra

Full name of responsible person

Dr. Ensiye Nasli-Esfahani

Street address

Diabetes and Metabolic Diseases Clinic, corner of Hayat St, Shahrivar St, Kargar Shomali

City

Tehran

Province

Tehran

Postal code

1411713137

Phone

+98 21 8833 8740

Email

dm_clinic@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Javad Hosseinzadeh

Street address

No. 44, Hojjatdoost Alley, Naderi St, Keshavarz Boulevard, Tehran University of Medical Sciences and Health Services, Faculty of Nutrition and Dietetics

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5975

Email

Info_snsd@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

60

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**

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Nourimajd

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 44, Hojjatdoost Alley, Naderi St, Keshavarz Boulevard, Tehran University of Medical Sciences and Health Services, Faculty of Nutrition and Dietetics

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5975

Email

s.nourimajd@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Esmailzadeh

Position

Professor of Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 44, Hojjatdoost Alley, Naderi St, Keshavarz Boulevard, Tehran University of Medical Sciences and Health Services, Faculty of Nutrition and Dietetics

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5975

Email

a.esmailzadeh@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Nourimajd

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 44, Hojjatdoost Alley, Naderi St, Keshavarz Boulevard, Tehran University of Medical Sciences and Health Services, Faculty of Nutrition and Dietetics

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Province

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Postal code

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Phone

+98 21 8895 5975

Email

s.nourimajd@gmail.com

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the participants' personal data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

Access period starts 8 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions and to those working in industry.

Under which criteria data/document could be used

No use or analysis of data and documentation is possible for any person.

From where data/document is obtainable

Dr. Ahmad Esmailzadeh is the supervisor of the project and the data will be preserved with him. If necessary, you can refer to the Faculty of Nutrition and Dietetics of Tehran University of Medical Sciences.

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

The request must be in the form of a letter and stamped by the relevant body or university, and after the necessary checks, the data will be provided to them.

Comments