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

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Iran (Islamic Republic of)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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

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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