Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

Pre-diabetic patients are reffered 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 Univercity of Medical Science

Street address

Daneshgah Street.,in front of 18 Ave.,Mashhad Univercity 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 109 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Mohsen Tafaghodi, Deputy of Research and Technology of Mashhad University of Medical Sciences
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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