

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of metabolic effects of probiotic supplementation on adults with pre-diabetic state

Protocol summary

Study aim

Evaluation of the effect of probiotic in glycemic and metabolic index on pre-diabetic patients

Design

A double-blind randomized clinical trial , group controlled , on 80 patients, randomized by Excel software.

Settings and conduct

In this double-blind randomized clinical trial, pre-diabetic patients referred to the endocrinology clinic of Loghman-e-Hakim Hospital are randomly divided into two groups of 40 people based on inclusion and exclusion criteria. After obtaining consent, in addition to lifestyle modification, in one group, a probiotic drug with the brand Biodiab will be used, and in the control group, a placebo drug (maltodextrin combination) will be used. In both groups, drugs will be prescribed every 12 hours for 3 months. Before and after the intervention, information will be recorded in questionnaire and serum samples will be collected. In this study, the main researcher, doctor and the person responsible for analysis the statistical data will be blinded , and the medication will be given to patient by a nurse.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 18 and 75 years old with impaired fasting blood sugar or impaired OGTT test. Exclusion criteria: pregnant women, usage of metformin or antibiotics during the study, use of probiotics within 30 days before study, patients with inflammatory bowel disease, celiac disease, liver cirrhosis, chronic alcohol consumption

Intervention groups

Patients are randomly divided into two groups, in addition to lifestyle modification, in a group probiotic drug under the trade name Biodiab , , product of Novagen with Tekgene Holdings ,,will be used and in controlled group placebo, which is a combination of maltodextrin, will be prescribed .

Main outcome variables

blood pressure; blood sugar; lipid profile ; Body mass

index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056553N1**

Registration date: **2022-11-30, 1401/09/09**

Registration timing: **prospective**

Last update: **2022-11-30, 1401/09/09**

Update count: **0**

Registration date

2022-11-30, 1401/09/09

Registrant information

Name

Saeid Kalbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5102 5582

Email address

saeidkalbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of metabolic effects of probiotic supplementation on adults with pre-diabetic state

Public title
Effect of probiotic in predaibetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
FBS 100-125 mg/dl Impaired OGTT test 2hours after using 75 grams of oral glucose
Exclusion criteria:
pregnant women Chronic alcohol consumption Patients with inflammatory bowel disease Patients with Live Cirrhosis Antibiotic usage during the study Patients with celiac disease Probiotic usage during 30 days before the study Usage of Metformin , anti diabetic agent or herbal medicine Corticosteroids usage

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sequence generation will be done by simple randomization and preparing and shuffling cards, so that 80 cards (40 cards with the symbol A and 40 cards with the symbol B) will be prepared and will be placed inside Sequentially Numbered Opaque Sealed Envelops (SNOSE) and will be shuffled. According to arrival eligible patients will choose an envelope, so that the relevant group is determined(patients will be unaware of each other's assigned group). The selected envelope will be separated from the rest of the envelopes. This process will be continued until the 80th patient, so that finally 40 patients will be placed in the intervention group and 40 patients in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the main researcher, doctor and the person responsible for analysis the statistical data will be blinded , and the medication will be given to patient by a nurse.Also, patients will be unaware of which type of medicine they are taking (probiotic or placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti of Medical Sciences
Street address
Yaman Ave
City
TEHRAN
Province
Tehran
Postal code
1985717443

Approval date
2022-11-06, 1401/08/15

Ethics committee reference number
IR.SBMU.MSP.REC.1401.388

Health conditions studied

1

Description of health condition studied
pre-diabetic state

ICD-10 code
R73.01

ICD-10 code description
Impaired fasting glucose

2

Description of health condition studied
pre-diabetic state

ICD-10 code
R73.02

ICD-10 code description
Impaired glucose tolerance (oral)

Primary outcomes

1

Description
fasting plasma glucose

Timepoint
Before the study and 90 days after intervention.

Method of measurement
Photometric method auto analyzer

2

Description

Blood sugar two hours after a meal

Timepoint

Before the study and 90 days after intervention.

Method of measurement

Photometric method auto analyzer

Secondary outcomes

1

Description

Body weight

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Body weight scale

2

Description

Systolic blood pressure

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Mercury pressure gauge

3

Description

Diastolic blood pressure

Timepoint

Mercury pressure gauge

Method of measurement

Before the study and 90 days after the intervention

4

Description

Body mass index

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Calculator

5

Description

Total Cholesterol

Timepoint

Before the study and 90 days after the intervention

Method of measurement

colorimetric method with auto-analyzer

6

Description

Low Density Lipoprotein

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Enzymatic method with auto analyzer

7

Description

Serum High Density Lipoprotein

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Enzymatic assay with autoanalyser

8

Description

Serum Triglycerides

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Enzymatic assay with autoanalyser

9

Description

HbA1c

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Chromatography

10

Description

High sensitive C-Reactive Protein

Timepoint

Before the study and 90 days after the intervention

Method of measurement

Turbidimetric Method

Intervention groups

1

Description

Intervention group: Pre diabetic patients receiving probiotic medicine under trade name Biodiab ,a product of Novagen pharmaceutical company with Tekgene Holding, every 12 hours for 3 months. According to the duration of the study, 180 capsules have been prepared for each person

Category

Prevention

2

Description

Pre diabetic patients receiving placebo, a maltodextrin composition , under trade name Biodiab ,a product of Novagen pharmaceutical company with Tekgene Holding, every 12 hours for 3 months, placebo in shape size color and packing is as same as probiotic. According to the duration of the study, 180 capsules have been prepared for each person

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman e Hakim

Full name of responsible person

Saeid Kalbasi

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Makhsous ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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shahid arabi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Novagen Pharmaceutical Company with Tekgen Holding

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Mahmoud Motalebi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Subspecialist

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position
resident
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Medical doctor
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
The data spss file includes groups and main and demographic variables
When the data will become available and for how long
After publication the article extracted from the plan
To whom data/document is available
Those who have corresponded with the author responsible for the plan and have enough reason to receive the file
Under which criteria data/document could be used
We have not made a decision on this matter and a decision will be made after reviewing the request
From where data/document is obtainable
Endocrine and metabolic disease research center of Loghman -e Hakim hospital ,Shahid Beheshti medical science , Tehran Saeid Kalbasi
email:saeidkalbasi@bums.ac.ir
What processes are involved for a request to access data/document
The applicant should send her/him request via email and after obtaining permission from all project partners, if the partners agree with her request, the data will be sent to her/him.
Comments