Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 been 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 probitic. According to the duration of the study, 180 capsules have been prepared for each person
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman e Hakim
Full name of responsible person
Saeid Kalbasi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Academic

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
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Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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