Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of probiotic supplementation on glycemic control, cardiometabolic risk factors, and endothelial function in overweight and obese subjects with pre-diabetes

Protocol summary

Study aim

1- Comparison of fasting serum glucose and insulin, HbA1c level and Homeostatic model assessment of insulin resistance (HOMA-IR) between two groups of intervention and placebo 2. Comparison of fasting serum levels of total cholesterol, triglyceride, HDL-C, LDL-C between two groups of intervention and placebo 3. Comparison of fasting serum levels of adiponectin, resistin, IL-6, TNF-α, Hs-CRP, ICAM and VCAM between two groups of intervention and placebo 4. Comparison of mean systolic and diastolic blood pressure between two groups of intervention and placebo

Design

Double-blind clinical trial with control group, with parallel design, and randomized with permuted-block randomizations

Settings and conduct

This study will be carried out in health centers and public health clinics of Semnan University of Medical Sciences. Food supplements and placebo will be prepared by the pharmaceutical company outside the research environment in sealed and non-transparent packaging, and will be available to researchers after encoding. Until the end of the study, patients and researchers will not be aware of the content of coding boxes.

Participants/Inclusion and exclusion criteria

Inclusion criteria were pre-diabetes diagnosis within the past 12 months, age between 35-65, and BMI between 25 and 40 kg/m2. Non-inclusion criteria include type 1 and type 2 diabetes, subjects treated with antibiotics over the past three months, people with digestive disorders, cardiovascular diseases, endocrine disorders, kidney dysfunction and malignancies, pregnant and lactating women, smokers, drug users, alcohol and drug users, regular consumption of food products and probiotic supplements, regular use of high-dose food supplements, and people with major changes in weight, diet and lifestyle in past three months.

Intervention groups

Intervention group: capsule containing probiotics Lactobacillus acidophilus and Bifidobacterium longum Placebo group: capsule containing maltodextrin, with similar shape, weight and size

Main outcome variables

The main outcome of this study is the levels of HbA1c. Other consequences include HOMA-IR levels and serum insulin , lipid profiles, adiponectin, resistin, TNF-α, IL-6, Hs-CRP, VCAM, and ICAM levels, and blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110510006431N3**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **prospective**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Mahdi Shadnoush

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 1423

Email address

shadnoush@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotic supplementation on glycemic control, cardiometabolic risk factors, and endothelial function in overweight and obese subjects with pre-diabetes

Public title
The effect of probiotic on metabolic disorders in subjects with pre-diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Pre-diabetes diagnosis within the last 12 months Age between 35-65 25<BMI<40 kg/m2
Exclusion criteria:
Type 1 and 2 diabetes People under treatment with any specific drug protocol including Metformin, Aspirin, OCPs or HRTs, immunosuppressives, and Corticosteroids People treated with antibiotics over the past three months People with digestive disorders, cardiovascular diseases, endocrine disorders, kidney dysfunction and malignancies Pregnant and lactating women, or those planning to become pregnant within the next 12 weeks Smokers, consumers of addictive drugs and alcohol Regular consumption of probiotic foods, or prebiotic and probiotic supplements over the past three months People with major changes in weight, diet and lifestyle over the past three months
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **85**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized to receive probiotic or placebo supplementation. Randomization will conduct based on permuted-block randomizations, stratified by gender and BMI. For this purpose, a random number table will be used. Allocation concealment will be performed by a statistician uninformed about the intervention and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients and the main investigators will not be aware of the type of intervention received in the two groups. Supplements and placebo will be prepared by the pharmaceutical company outside the research environment in sealed and non-transparent packaging, and will be available to researchers after encoding. Until the end of the study, patients and researchers will not be aware of the content and method of coding supplementation and placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethnical Committee of Semnan University of Medical Sciences
Street address
Head of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan
City
Semnan
Province
Semnan
Postal code
35198-99951
Approval date
2018-02-06, 1396/11/17
Ethics committee reference number
IR.SEMUMS.REC.1396.234

Health conditions studied

1

Description of health condition studied
prediabetes
ICD-10 code
R73.0
ICD-10 code description
Abnormal glucose tolerance test, Prediabetes

Primary outcomes

1

Description

HbA1c

Timepoint

At the beginning and following 12 weeks supplementation

Method of measurement

HPLC method

Secondary outcomes

1

Description

Fasting serum insulin

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

2

Description

HOMA-IR

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

Calculation

3

Description

Fasting serum total cholesterol

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

biochemical assay kits

4

Description

Fasting serum triglyceride

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

biochemical assay kits

5

Description

Fasting serum LDL cholesterol

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

biochemical assay kits

6

Description

Fasting serum HDL cholesterol

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

biochemical assay kits

7

Description

Fasting serum adiponectin

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

8

Description

Fasting serum resistin

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

9

Description

Fasting serum IL-6

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

10

Description

Fasting serum TNF-α

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

11

Description

Fasting serum ICAM-1

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

12

Description

Fasting serum VCAM-1

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

ELISA

13

Description

systolic blood pressure

Timepoint

The beginning of the study and the end of 12 weeks

Method of measurement

calibrated blood pressure monitor

14

Description
diastolic blood pressure
Timepoint
The beginning of the study and the end of 12 weeks
Method of measurement
calibrated blood pressure monitor

Intervention groups

1

Description
Intervention group: Probiotic supplements will be provided in the form of capsules containing Lactobacillus acidophilus and Bifidobacterium longum in a colony-forming units of 10*9. All participants is this group are asked to take the capsule daily with a glass of water for 12 weeks.
Category
Other

2

Description
Control group: All participants is this group are asked to take the capsule daily with a glass of water for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers and public Clinics of Semnan Province
Full name of responsible person
Mahdi Shadnoush
Street address
Head of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan
City
Semnan
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Semnan
Postal code
35198-99951
Phone
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Email
shadnoush@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Ali Rashidy-pour
Street address
Head of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan
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Email
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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
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Mahdi Shadnoush
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Head of Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan
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Email
shadnoush@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Mahdi Shadnoush

Position
Associate professor

Latest degree
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Person responsible for updating data

Contact

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Semnan University of Medical Sciences

Full name of responsible person
Mahdi Shadnoush

Position
Associate professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Information on the main outcome and secondary outcomes will be published.

When the data will become available and for how long
The start of access period will be after the publication of the results in 1398

To whom data/document is available
All academic researchers and health professionals

Under which criteria data/document could be used
Not currently set.

From where data/document is obtainable
Not currently set.

What processes are involved for a request to access data/document
Not currently set.

Comments