Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of probiotic on serum adiponectin level in pre-diabetic patients

Protocol summary

Study aim
The effect of probiotic on serum adiponectin level in pre-diabetic patients.

Design
کارآزمایی بالینی دارای گروه کنترل، با گروه های موازی ، سه سویه کور ، تصادفی شده

Settings and conduct
At first, physical examination including height, weight and BMI is performed in the patients and then referred to the laboratory for measurement of Insulin-FBS-LDL-HDL-TG-HBA1C. In the present study, in addition to the above-mentioned tests, serum levels of adiponectin were also measured. Subsequently, patients are randomly divided into two groups, one group receiving probiotic tablets exceeding CFU 109 equivalent to 500 mg capsules daily, and the other group being given placebo. BMI is effective on adiponectin levels, with patients randomized based on BMI. After three months, the effect of the above treatment on primary laboratory parameters, systolic and diastolic blood pressure and BMI in both groups will be compared. The probiotic regimen is lactocare containing lactase and lactobacillus acidophilus. Placebo capsule The placebo drug is also a capsule that looks exactly like the drug. At the beginning of the plan, a full explanation of the effect of diet and exercise is given to all patients. Physical activity times are recommended three times a week. Patients are given diet charts.

Participants/Inclusion and exclusion criteria
inclusion All prediabetic patients aged 30 to 65 years exclusion Patients with previously diagnosed diabetes treated with hypoglycemic drugs such as metformin and such Patients with a prior diagnosis of pre-diabetes who are under medication treatment

Intervention groups
The intervention group received probiotics and the control group received placebo

Main outcome variables
Patient weight and BMI measurements, systolic and diastolic blood pressures, blood glucose test findings, HDL, LDL, HBA1C and adiponectin at baseline and thirty months after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190801044405N1**
Registration date: **2020-10-25, 1399/08/04**
Registration timing: **prospective**

Last update: **2020-10-25, 1399/08/04**
Update count: **0**

Registration date
2020-10-25, 1399/08/04

Registrant information

Name
mehrdad sarabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3601 3644

Email address
mehrdad.sarabi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-14, 1399/10/25

Expected recruitment end date
2021-07-16, 1400/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of probiotic on serum adiponectin level in pre-diabetic patients

Public title
The effect of probiotic on serum adiponectin level in pre-diabetic patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All prediabetic patients aged 30 to 65 years

Exclusion criteria:
Patients with previously diagnosed diabetes treated with hypoglycemic drugs such as metformin and such
Patients with a prior diagnosis of pre-diabetes who are under medication treatment

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, a physical examination including height, weight, BMI, and systolic and diastolic blood pressure are performed in patients. Patients are referred to the laboratory for measurement of Insulin-FBS-LDL-HDL-TG-HBA1C. Serum levels of adiponectin are also measured in the following tests. Patients are then randomly divided into two groups, one group receiving probiotic pills more than 109 CFU equivalent to 500 mg capsules daily and the other group receiving placebo. Also, given that BMI is effective on adiponectin levels, patients are randomized based on their BMI.

Blinding (investigator's opinion)
Triple blinded

Blinding description
We used odd numbers for the main drug and even numbers for placebo, patients pick a card and based on number of their card our assistant give them a pack of placebo or drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Azadi Square, east door of Ferdowsi University campus, Faculty of Medicine

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2019-04-09, 1398/01/20

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.154

Health conditions studied

1

Description of health condition studied
diabetes

ICD-10 code
R73.09

ICD-10 code description
Other abnormal glucose

Primary outcomes

1

Description
Serum adiponectin levels

Timepoint
Before intervention and after 3 months of medication

Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:500mg capsules of Lactocare probiotic for 3 month, 1 capsule daily

Category
Prevention

2

Description
Control group: 500mg placebo capsules for 3 month, 1

capsule daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mina Akbari Arad

Street address

Khorasan Razavi, Mashhad, Ahmadabad St., Ghaem Hospital

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91766-99199

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Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah Avenue - Mashhad University of Medical Sciences-Vice chancellor for research and technology

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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

Vice chancellor for research, 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

Mina Akbari Rad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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