

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of probiotic supplementation on lipoprotein-associated phospholipase A2 in type 2 diabetic patients

Protocol summary

Study aim

To determine the effect of probiotic supplementation on lipoprotein-associated phospholipase A2 in type 2 diabetic patients

Design

This study is a 12-week randomized, double-blinded, placebo-controlled clinical trial among populations with T2DM, aged 50-65 years old, in Sulaymaniyah, Iraq.

Settings and conduct

This study is a 12-week randomized, double-blinded, placebo-controlled clinical trial among populations with T2DM, aged 50-65 years old, in Sulaymaniyah, Iraq.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients aged between 50 - 65 years. who their BMI between 25 - 34.9 kg/m² Exclusion criteria: - Irregular diet and unstable body weight - History of Cardiovascular disease, stroke, Thyroid disease, and other chronic diseases - Dietary supplementation of probiotics within 6 months before screening - Pregnancy or breast-feeding - Antibiotic users.

Intervention groups

This study of patients with type 2 diabetes referred to the Shar hospital, Sulaymaniyah, Iraq, which has the inclusion criteria at the beginning of the study goals, will be explained to participants, and written consent will be obtained from all participants volunteer patients. Participants will be divided into two groups receiving probiotic supplements (n=34) and placebo groups (n=34) by the balanced randomized blocked method. Supplements will be either placebo (Placebo; containing starch and inactive ingredient excipients) or probiotics with dosages of Bacillus Coagulans, Lactobacillus Plantarum, Lactobacillus acidophilus, and Bifidobacterium bifidum, 3 billion/capsules (3×10⁹ colony forming units (CFU) per capsule).

Main outcome variables

[Lp-PLA2] and [fasting serum levels of insulin, glucose, TG, TC, LDL, and HDL, and HOMA-IR]

General information

Reason for update

Acronym

Lp-PLA2 , T2D

IRCT registration information

IRCT registration number: **IRCT20210529051435N1**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Salman Jaff

Name of organization / entity

Country

Iraq

Phone

+964 53 328 8335

Email address

salmanjaff86@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic supplementation on lipoprotein-associated phospholipase A2 in type 2 diabetic patients

Public title

probiotic in diabetes

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 50 - 65 years Type 2 diabetic patients that diagnosed at least 2 years ago. BMI between 25 - 34.9 kg/m² The patient or caregiver understands the objectives of the study and agrees to follow the necessary rules throughout the study.

Exclusion criteria:

Irregular diet and unstable body weight (body-weight change > 5% within 3 months before screening) Type 1 diabetes or non-diabetic patients History of Cardiovascular disease, Hypertension, heart attack, angina pectoris, cerebrovascular disease, stroke, Thyroid disease, and other chronic diseases and transmitted diseases in the past year. Dietary supplementation of probiotics within 6 months before screening Pregnancy or breast-feeding Use of smoke and alcohol during the last three months prior the study. Consumption of medication that affects body weight, energy expenditure, glucose control, or antibiotic treatment within 3 months before screening. using any drug other than metformin, sulfonylurea, statins, angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), and aspirin at doses of 80 mg or less Changing in medications received in the previous three months. Having any allergic reaction after our intervention. Participants who consume less than 80% of the supplement. Further exclusion criteria are acute or chronic infections, liver disease, kidney disease, gastrointestinal disease, or any other acute or chronic disease requiring treatment.

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a double-blind, randomized, parallel, placebo-controlled clinical trial. Sixty-eight diabetic patients are randomly allocated in a ratio of 1:1 into the intervention and control groups by permuted block randomization. We used stratified randomization to match participants based on sex and menopausal in both groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, Participants will be divided into two groups receiving probiotic supplement (n=34) and placebo groups (n=34) by the balanced randomized blocked method. Supplemnts will be either placebo (Placebo; containing starch and inactive ingredient excipients) or probiotics with dosages of Bacillus Coagulans, Lactobacillus Plantarum, Lactobacillus acidophilus, and Bifidobacterium Bifidum, 3 billion/capsules (3×10⁹ colony forming units (CFU) per capsule). Both probiotics and placebo capsules will be produced and coded by Takgene Zist pharmaceutical company. The packaging, odor, and appearance of a placebo containing Biodiab are just similar to the supplement containing Biodiab.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of school of medicine - Tehran university of medical sciences

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Number 44, East Hoojztdoust, Naderi St., School of Nutritional Sciences and Dietetics

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Tehran

Province

Tehran

Postal code

1416643931

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.702

Health conditions studied**1****Description of health condition studied**

Type 2 Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Lipoprotein-associated phospholipase A2 (Lp-PLA2)

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

using a lab kit to measure Lp-PLA2

Secondary outcomes

1

Description

Glycemic Index(Fasting Blood Sugar, Glycosylated Hemoglobin)

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

enzymatic colorimetric method

2

Description

Lipid Profile (TC, TG, HDL, LDL)

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

enzymatic colorimetric method

3

Description

HOMA-IR

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

Calculating by formula: $HOMA-IR = (glucose(mg/dl) \times Insulin(\mu U/ml)) / 22.5$

4

Description

weight

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

standard scale

5

Description

waist circumference

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

non-stretching tape

6

Description

Body composition

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

Bioelectrical Impedance Analysis

Intervention groups

1

Description

Intervention group: This study of patients with type 2 diabetes referred to the Shar hospital, Sulaymaniyah, Iraq, which has the inclusion criteria, at the beginning of the study goals, will be explained to participants, and then written consent will be obtained from all-volunteer patients. Participants will be divided into two groups receiving probiotic supplements (n=34) and placebo groups (n=34) by the balanced randomized blocked method. Supplements will be probiotics with dosages of Bacillus Coagulans, Lactobacillus Plantarum, Lactobacillus acidophilus, and Bifidobacterium bifidum, 3 billion/capsules (3×10^9 colony forming units (CFU) per capsule). The probiotic capsules will be produced and coded by Takgene Zist pharmaceutical company. The timeframe for intervention will be 12 weeks.

Category

Treatment - Other

2

Description

Control group: The placebo group (n=34) (Placebo; containing starch and inactive ingredient excipients) The placebo capsules will be produced and coded by Takgene Zist pharmaceutical company. • The packaging, odor, and appearance of placebo containing Biodiab are just similar to the supplement containing Biodiab. • Each Capsule will be taken orally with a full glass of water. • Participants from each group will take one Biodiab capsule daily. The timeframe for intervention will be 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

diabetic center in Sulaymaniyah

Full name of responsible person

Salman Jaff

Street address

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Web page address

https://www.facebook.com/427167710818804

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kurosh Djafarian

Street address

keshavarz blvd

City

Tehran

Province

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1417653911

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Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Salman Salih Mohammed Jaff

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Kurosh Djafarian

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Person responsible for updating data

Contact

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Latest degree

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Other areas of specialty/work

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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

Yes - There is 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

Title and more details about the data/document

-not clear yet

When the data will become available and for how long

one year after publishing results

To whom data/document is available

Academic staffs

Under which criteria data/document could be used

comparison analyses

From where data/document is obtainable

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What processes are involved for a request to access data/document

-formal request from main investigator Data will be sent
after one month

Comments

none