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 between50 - 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

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+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 between50 - 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. Suppelemnts will be either placebo (Placebo; containing starch and inactive ingredient excipients) or probiotics with dosages of Bacillus Coagulans, Lactobacillus Plantarum, Lactobacillus acidophilus, and Bifidobacterium Bifdum, 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

Street address
Number 44, East Hojjatdoust, Naderi St., School of Nutritional Sciences and Dietetics

City
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)× Insulin(µU/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,s 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 (3×109 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
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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

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keshavarz blvd

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Tehran

Province

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1417653911

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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

Name of organization / entity

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Full name of responsible person

Kurosh Djafarian

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Professor

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Nutrition

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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
-Professor Kurosh Djafarian Clinical Nutrition Department School of Nutritional Sciences and Dietetics Tehran University of Medical Sciences, Tehran, Iran Tel: +98 21 42933036, Fax: +98 21 88974462 E-mail address: kdjafarian@tums.ac.ir
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