Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of probiotic supplementation on lipid profile, markers of insulin metabolism, biomarkers of inflammation and oxidative stress factors in patients with diabetes nephropathy

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of probiotics supplementation on lipid profile, markers of insulin metabolism, biomarkers of inflammation and oxidative stress factors in patients with diabetes nephropathy.

Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive probiotic (n=30) or placebo (n=30). Probiotic and placebos capsules are similar in shape and size.

Settings and conduct

Among patients with diabetic nephropathy referred to Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic nephropathy and aged 45 to 85 years will be included in this study.Exclusion criteria:History of active infection within 3 months, intake of probiotic and/or synbiotic supplements within 3 months, history of hospital admission within 3 months, malignancy and/or liver cirrhosis.

Intervention groups

Intervention group: Probiotic supplements containing four strains of Lactobacillus acidophilus (2×109 CFU/g),Lactobacillus fermentum (2×109 CFU/g),Bifidobacterium bifidum (2×109 CFU/g),Lactobacillus reuteri (2×109 CFU/g), daily, for 12 weeks orally. Control group: Placebo, daily, for 12 weeks orally.

Main outcome variables

Outcomes: Insulin metabolism parameters (primary outcomes) and lipid profiles,biomarkers of inflammation and oxidative stress factors (secondry outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061134458N1**
Registration date: **2017-06-21, 1396/03/31**
Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**
Update count: **1**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name

Alireza Mafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7052

Email address

armafi@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-05-15, 1396/02/25

Expected recruitment end date

2017-06-15, 1396/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic supplementation on lipid profile, markers of insulin metabolism, biomarkers of inflammation and oxidative stress factors in patients with diabetes nephropathy

Public title

Effect of supplementation in treatment of patients with diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic nephropathy aged 45 to 85 years

Exclusion criteria:

History of active infection within 3 months Intake of probioticand/or synbiotic supplements within 3 months History of hospitaladmission within 3 months Malignancy and/or liver cirrhosis

Age

From **45 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to receive supplement or placebo. Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

88715973474

Approval date

2017-04-30, 1396/02/10

Ethics committee reference number

IR.Kaums.REC.1396.43

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

N08.3

ICD-10 code description

Glomerular disorders in diabetes mellitus (E10-E14 with common fourth character .2+)

Primary outcomes

1

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Triglyceride

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

HDL-cholesterol

Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

5

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
HbA1c
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Serum Creatinine
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

11

Description
Blood Urea Nitrogen
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

12

Description
urine protein
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

13

Description
Expressed levels of PPAR-γ gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Real-time PCR

14

Description
Expressed levels of LDL receptor gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Real-time PCR

15

Description
Expressed levels of interleukin-1gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Real-time PCR

16

Description
Expressed levels of TNF-a gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Real-time PCR

17

Description
Expressed levels of TGF-B gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Real-time PCR

18

Description
advanced glycosylation end-products
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Fluorometric method

19

Description
Serum insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Probiotic supplements containing four strains of Lactobacillus acidophilus (2×109 CFU/g),Lactobacillus fermentum (2×109 CFU/g),Bifidobacterium bifidum (2×109 CFU/g),Lactobacillus reuteri (2×109 CFU/g), daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo, daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Clinic
Full name of responsible person
Zatollah Asemi
Street address
Ghotbe Ravandi Boulevard, Kashan
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kashan
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Isfehan
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88715973474
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asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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Ghotbe Ravandi Boulevard, Kashan
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88715973474
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Email
research@kaums.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, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person

Zatollah Asemi

Position

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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

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