Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Clinical trial of the effect of synbiotic supplementation compared with the placebo on metabolic profiles in diabetic hemodialysis patients

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of synbiotic supplementation on metabolic profiles in diabetic hemodialysis patients.

Design

Study design: randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive supplement (n=30) or placebo (n=30).

Settings and conduct

Among diabetic hemodialysis patients referred to Akhavan Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 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. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic hemodialysis patients; aged 18 to 80 years. Exclusion criteria:Taking probiotic and/or synbiotic supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment, required changes in medications during the study and recent diabetes diagnosis.

Intervention groups

Intervention group: Synbiotic oral capsule containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g) (Tak Gen Zist, Tehran, Iran), 0.8 g inulin, daily, for 12 weeks. Control group: Placebo oral capsule (Tak Gen Zist, Tehran, Iran), daily, for 12 weeks.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090133941N17**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-16, 1398/06/25**
Update count: **1**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2017-11-15, 1396/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of synbiotic supplementation compared with the placebo on metabolic profiles in diabetic hemodialysis patients

Public title

Effect of synbiotic supplementation in treatment of diabetic hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic hemodialysis patients Aged 18 to 80 years

Exclusion criteria:

Taking probiotic and/or synbiotic supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment Required changes in medications during the study and recent diabetes diagnosis

Age

From **18 years** old to **80 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 (<25 and ≥25 kg/m2) and age (<50 and ≥50 y), 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

Ilam

Postal code

8115187159

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.44

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

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

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

HDL

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

Glutathione

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

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

9

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

Intervention groups

1

Description

Intervention group: Synbiotic oral capsule containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g) (Tak Gen Zist, Tehran, Iran), 0.8 g inulin, daily, for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo oral capsule (Tak Gen Zist, Tehran, Iran), daily, for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaee Avenue, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5546 3378

Email

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

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Email
hamidi-gh@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
Ph.D of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Fax

Email
asemi_r@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
Ph.D of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Fax

Email
asemi_r@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
Ph.D of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Fax

Email
asemi_r@yahoo.com

Web page address

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