Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

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

Protocol summary

Study aim

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

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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic hemodialysis aged 18 to 80 years. Exclusion criteria: Pregnant women, intestinal diseases, taking probiotic supplements and other forms of probiotics including probiotic yogurt, kefir and other fermented foods, taking prebiotic, antioxidant and/or anti-inflammatory supplements such as vitamin E, vitamin C and omega-3 fatty acids, taking antibiotics, immunosuppressive medications within 3 months prior to the enrollment in the study.

Intervention groups

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

Main outcome variables

Outcomes: Glycemic control (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

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201603185623N69**
Registration date: **2016-03-23, 1395/01/04**
Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**
Update count: **1**

Registration date

2016-03-23, 1395/01/04

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2016-02-29, 1394/12/10

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Effect of supplementation in treatment of patients with diabetic hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Patients with diabetic hemodialysis aged 18 to 80 years.
Exclusion criteria:
Pregnant women Intestinal diseases Taking probiotic supplements and other forms of probiotics including probiotic yogurt, kefir and other fermented foods Taking prebiotic, antioxidant and/or anti-inflammatory supplements such as vitamin E, vitamin C and omega-3 fatty acids Taking antibiotics, immunosuppressive medications within 3 months prior to the enrollment in the study
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 and age, subjects will be randomly divided into two groups to take supplementation (n=30) or placebo (n=30). 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
8115187159
Approval date
2016-03-09, 1394/12/19
Ethics committee reference number
IR.Kaums.REC.1394.166

Health conditions studied

1

Description of health condition studied
همودیالیز
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease

Primary outcomes

1

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

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calcution using HOMA formula

Secondary outcomes

1

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

2

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

3

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

4

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

5

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

6

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

7

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

8

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

9

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

10

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

11

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

12

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

13

Description
LDL
Timepoint
At the beginning of the study and 12 weeks after the intervention

Method of measurement
Enzymatic kit

14

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

15

Description
Sodium
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Flame photometry

16

Description
Potassium
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Flame photometry

17

Description
Hemoglobin A1c
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Glycomat kit

Intervention groups

1

Description
Intervention group: Probiotic supplements containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (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
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 5554 0022
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
Associate professor

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

Email
asemi_r@yahoo.com

Person responsible for scientific 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

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
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ghotbe Ravandi Boulevard, Kashan

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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