

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of synbiotic supplementation on plasma levels of Advanced Glycation End Products and cardiovascular risk factors in hemodialysis patients: a double-blind clinical trial

Protocol summary

Study aim

Determining the effect of synbiotic supplementation on plasma levels of advanced glycation end products and cardiovascular risk factors in hemodialysis patients

Design

During a 12-week intervention, the intervention group received two synbiotic capsules daily after lunch and dinner, while the control group received two placebo capsules daily.

Settings and conduct

This randomized, double-blind, placebo-controlled clinical trial will be performed at the main dialysis center of Farabi Specialized and Sub-Specialized Hospital in Isfahan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: HD treatment at least twice a week for a maximum of 4 hours each time, HD treatment for at least 6 months before, no pregnancy or lactation, no immune deficiency, no history of active cancers, no history of disease Severe chronic and acute medical conditions such as lung disease, cardiovascular disease, liver and acute pancreatitis, non-addiction and consumption of alcohol or drugs, lack of severe digestive disorders and diseases, HIV disease, mental health problems, ability to drink at least 200 ml of water Day, life expectancy and survival for at least 3 months and confirmation of written consent. Exclusion criteria: Patients with severe edema, people who had an infection 4 weeks ago, people who used synbiotics, probiotics, prebiotics or antibiotics during the 4 weeks before the study, people who are candidates for kidney and organ transplants or Peritoneal dialysis during 3 months of study, taking immunosuppressive drugs or anticoagulants and chemotherapy drugs, sensitivity to complementary components, patient's unwillingness to participate in the study, failure to fully answer questions or report side effects from use synbiotics.

Intervention groups

hemodialysis patients

Main outcome variables

Plasma levels of Advanced Glycation End Products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131013014994N7**

Registration date: **2022-04-27, 1401/02/07**

Registration timing: **prospective**

Last update: **2022-04-27, 1401/02/07**

Update count: **0**

Registration date

2022-04-27, 1401/02/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

abdollahzad@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplementation on plasma levels of Advanced Glycation End Products and cardiovascular risk factors in hemodialysis patients: a double-blind clinical trial

Public title

The effect of synbiotic supplementation on plasma levels of Advanced Glycation End Products and cardiovascular risk factors in hemodialysis patients: a double-blind clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Perform HD treatment at least twice a week for a maximum of 4 hours each time Treatment under HD for at least 6 months No pregnancy or breastfeeding No immune system defects No history of active cancers No history of severe chronic diseases and acute medical conditions such as lung disease, cardiovascular disease, liver disease and acute pancreatitis No addiction to alcohol or drugs Lack of severe digestive disorders and diseases, HIV disease, mental problems Ability to drink at least 200 ml of water per day Life expectancy and survival for at least 3 months Confirmation of written consent

Exclusion criteria:

Patients with severe edema People who had infection 4 weeks ago People who took synbiotics, probiotics, prebiotics, or antibiotics during the 4 weeks before the study Candidates for kidney and organ transplantation or peritoneal dialysis during 3 months of study Taking immunosuppressive drugs or anticoagulants and chemotherapy drugs Sensitivity to complementary compounds The patient's unwillingness to participate in the study Lack of complete answers to questions Report side effects from taking synbiotics

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: 34

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be assigned to the two intervention and placebo groups after signing the informed consent form through random blocks of 4

people and in a one-to-one ratio using RAS software. The randomization process is performed by a statistician and patients and researchers will be blinded to the process. Individuals will be matched at the beginning of the study based on diet, sex, age, and duration of dialysis in each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

For this double-blind study, placebo and synbiotic capsules are coded A and B by the supplement provider. The codes are kept in a sealed envelope so that patients and researchers will be blinded by how they are assigned to the supplement or placebo and the study arms until the end of the study. Synbiotic and placebo capsules will be the same size, color, odor and packaging.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Boulevard - Central Building of Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2022-04-12, 1401/01/23

Ethics committee reference number

IR.KUMS.REC.1401.033

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

hemodialysis patients

ICD-10 code

R88.0

ICD-10 code description

Cloudy (hemodialysis) (peritoneal) dialysis effluent

Primary outcomes

1

Description

Plasma levels of advanced glycation end products in hemodialysis patients

Timepoint

First study (before the intervention) and end of the study (end of week 12)

Method of measurement

Blood sample- Advanced Glycation End Products (AGE)
ELISA Kit

Secondary outcomes

1

Description

Plasma homocysteine levels in hemodialysis patients

Timepoint

Beginning of the study (before the intervention) and end of the study (end of week 12)

Method of measurement

Blood sample - High performance liquid chromatography

2

Description

Plasma fibrinogen levels in hemodialysis patients

Timepoint

Beginning of the study (before the intervention) and end of the study (end of week 12)

Method of measurement

Blood sample - coagulation factor

3

Description

Gastrointestinal function

Timepoint

Beginning of the study (before the intervention) and end of the study (end of week 12)

Method of measurement

THE GASTROINTESTINAL SYMPTOM RATING SCALE (GSRs)

4

Description

Fasting blood sugar and HgA1C

Timepoint

Beginning of the study (before the intervention) and end of the study (end of week 12)

Method of measurement

Blood sample

Intervention groups

1

Description

During a 12-week intervention in hemodialysis patients, the intervention group received two synbiotic capsules daily, after lunch and dinner. Each synbiotic capsule

(under the brand name GeriLact; Bio Fermentation Company, Tehran, Iran) contains Lactobacillus rhamnosus, Lactobacillus casei, Lactobacillus acidophilus, Lactobacillus bulgaricus, Lactobacillus fermentum, Lactobacillus plantarum and Lactobacillus plantarum at a dose of 10(9) CFU (10 to the power of 9 CFU) as a probiotic and 21 mg of fructooligosaccharide as a prebiotic..

Category

Treatment - Drugs

2

Description

In patients undergoing hemodialysis in the control group, two placebo capsules daily (Bio Fermentation Company, Tehran, Iran) after lunch and dinner (each capsule contains 350 mg of inulin, maltodextrin and all excipients in the synbiotic product except the active ingredient) Will receive. Synbiotic and placebo capsules will be the same size, color, odor and packaging.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Esfahan Farabi Hospital

Full name of responsible person

Dr hamid mohammad beigi

Street address

Mushtaq third street, Arghavanieh boulevard

City

Esfahan

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Isfahan

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farabih@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

reza khodarahmi

Street address

Shahid Beheshti Boulevard, Building No. 2, Deputy of Research and Technology

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Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Hadi Abdollahzad

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Isaar Square, Faculty of Nutrition Sciences and Food Industry

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Person responsible for scientific inquiries

Contact

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Kermanshah University of Medical Sciences

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
yasaman azamian

Position
masters

Latest degree
Bachelor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available