Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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 plantarus 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Position
masters
Latest degree
Bachelor
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Kermanshah
Postal code
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Email
yasaman_azamian@yahoo.com

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