Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

investigating the effect of probiotic supplements on blood pressure changes in patients undergoing hemodialysis Randomized clinical trial

Protocol summary

Study aim
Determining the effect of single and multi-strain probiotic supplements on blood pressure changes in patients undergoing hemodialysis at Namazi Hospital, Shiraz

Design
This study will be done on 136 patients undergoing hemodialysis in the age range of 18-70 years in four groups (34/group): placebo, L. Plantarum, Streptococcus thermophilus, and L. plantarum, Streptococcus thermophilus groups. In two groups, single probiotics are administered separately, each with a dose of CFU:1*109, and in the third group, a combination of two probiotics with CFU:2*109 is administered orally for 12 weeks. Patients use the drug/day at noon and on dialysis days after dialysis. The arterial blood pressure of patients undergoing dialysis is taken and recorded in three stages before, during, and after dialysis. A venous blood sample is taken from all the studied patients before and after 12 weeks. The resulting plasma is stored at a temperature of -80. In order to investigate the mechanism of the effect of probiotics in changing or not changing arterial blood pressure, plasma markers such as CBC, C-reactive protein, angiotensin-converting enzyme, total antioxidant capacity, and total oxidant capacity will be measure in the plasma sample

Settings and conduct
136 patients undergoing hemodialysis from Namazi and Abu Ali Sina hospitals are divided into four groups by block randomization method.

Participants/Inclusion and exclusion criteria
Patients with chronic renal failure undergoing hemodialysis in Namazi Hospital and Abu Ali Sina Hospital are included in the study. Patients with active cancer, active infection, pregnancy, or allergy to probiotic compounds are excluded from the study

Intervention groups
Placebo, L. plantarum, Streptococcus thermophilus, and L. plantarum + Streptococcus thermophilus groups

Main outcome variables
Arterial blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230701058626N1**
Registration date: **2023-11-30, 1402/09/09**
Registration timing: **prospective**

Last update: **2023-11-30, 1402/09/09**
Update count: **0**

Registration date
2023-11-30, 1402/09/09

Registrant information

Name
Zeinab Karimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3612 2264

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-12, 1402/09/21

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
investigating the effect of probiotic supplements on blood pressure changes in patients undergoing hemodialysis Randomized clinical trial

Public title
investigating the effect of probiotic supplements on blood pressure changes in patients undergoing hemodialysis at Namazi Hospital in Shiraz. Randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic kidney disease who undergo hemodialysis for more than three months are included in the study

Exclusion criteria:
Active cancer Active infection Pregnancy Sensitivity to probiotic compounds

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **152**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be done using the permutation blocks method using the site www.sealedenvelop.com based on 38 random blocks of size 4 for the calculated sample size of 152 people, and the random sequence generated is prepared in the EXCEL file.

Blinding (investigator's opinion)
Double blinded

Blinding description
Medicines and placebo are given to the nurses of the dialysis department in completely similar packages (marked with numbers one to four) based on block randomization, and they are not aware of the contents of the packages. Based on the numbers and list of patients, he distributes medicines and placebo to the patients, and the patients do not know about the contents of the packages. The analyzer knows the contents of the packets

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz, Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2023-11-12, 1402/08/21

Ethics committee reference number
IR.SUMS.REC.1402.386

Health conditions studied

1

Description of health condition studied
Hemodialysis patients

ICD-10 code
Z99.2

ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
Arterial blood pressure

Timepoint
before and after treatment

Method of measurement
Arterial blood pressure of patients undergoing dialysis is taken and recorded in three stages before, during and after dialysis.

Secondary outcomes

1

Description
1. Determining the average arterial blood pressure before, during, and after receiving probiotics and placebo in experimental groups

Timepoint
before, during, and after receiving probiotics and placebo

Method of measurement

Digital pressure gauge

2

Description
Determining the average angiotensin-converting enzyme (ACE) activity before and after receiving probiotics and placebo in experimental groups.
Timepoint
before and after receiving probiotics and placebo
Method of measurement
Spectrophotometry

3

Description
Determining the average total antioxidative capacity (TAC), and total oxidative state (TOS) measure before and after receiving probiotics and placebo in experimental groups.
Timepoint
before and after receiving probiotics and placebo
Method of measurement
Spectrophotometry

4

Description
Determining the average complete blood count (CBC) before and after receiving probiotics and placebo in experimental groups
Timepoint
before and after receiving probiotics and placebo
Method of measurement
Autolyzer

Intervention groups

1

Description
Sachet containing probiotic L-Plantarum with a dose of 1*109, to be taken orally one sachet daily for 12 weeks.
Category
Treatment - Drugs

2

Description
A sachet containing the probiotic Streptococcus thermophilus with a dose of 1*109 to be taken orally once a day for 12 weeks.
Category
Treatment - Drugs

3

Description
A sachet containing a combination of two probiotics, L. plantarum and Streptococcus thermophilus, with a dose of 2*109, which should be taken orally for 12 weeks.
Category
Treatment - Drugs

4

Description
Control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Centers of Namazi Hospital
Full name of responsible person
Maryam shafie
Street address
Zand St., Namazi Square, Namazi Medical Education Center
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2

Recruitment center
Name of recruitment center
Abo -Ali Sina Charity Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Zeinab Karimi

Position
Assistant

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for scientific inquiries

Contact

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the effects of probiotics on blood pressure values in dialysis patients will be shared

When the data will become available and for how long

After publication of the article

To whom data/document is available

All researchers

Under which criteria data/document could be used

For guidance for research in this field and in the form of general results

From where data/document is obtainable

The corresponding author of the article - Shiraz Nephro-urology l Research Center

What processes are involved for a request to access data/document

The corresponding author of the article - Shiraz Nephro-urology l Research Center

Comments