

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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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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 1×10^9 , 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 1×10^9 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 2×10^9 , 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

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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

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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 I Research Center

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

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

Comments