

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effect of *Streptococcus thermophilus*, *Lactiplantibacillus plantarum* and the combination of these two probiotics on uremic pruritus in patients undergoing hemodialysis : A double-blind randomized clinical trial

Protocol summary

Study aim

Investigating the effect of probiotics on uremic pruritus in patients under hemodialysis.

Design

clinical trial with control group, parallel, double-blinded, and randomized, phase 3 on 56 patients(each group 14). Initially, block randomization will be performed. The four study groups will include :1.Placebo maltodextrin2.Lactiplantibacillus plantarum 3.Streptococcus Thermophilus 4.Combination of two probiotic.

Settings and conduct

Patients at dialysis centers affiliated with Shiraz University of Medical Sciences will be studied in a double-blind manner. The drugs and placebo will be provided to the nurse in similar packaging based on block randomization and will be distributed according to their numbers and the patient list. The patients and the researcher responsible for data collection will have no knowledge of the contents of the packages. To assess itching, the visual analog scale method and the Persian version of the 5-D itch questionnaire will be used,to assess the quality of life of skin patients, the Persian version of the Dermatology Quality of Life Index questionnaire will be used. Serum levels of C-reactive protein and interleukin-6 will be measured before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: more than three months of continuous hemodialysis with at least 6 weeks of itching. Exclusion criteria: active cancer or infection, pregnancy, or sensitivity to probiotics.

Intervention groups

1.patients with uremic pruritus receiving the maltodextrin placebo. 2.patients with uremic pruritus receiving the probiotic *Lactiplantibacillus Plantarum*.

3.patients with uremic pruritus receiving the probiotic *Streptococcus Thermophilus*. 4.patients with uremic pruritus receiving the combined two probiotics mentioned above.

Main outcome variables

severity of itching;quality of life score; serum levels of interleukine-6 and C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048927N1**

Registration date: **2025-04-27, 1404/02/07**

Registration timing: **registered_while_recruiting**

Last update: **2025-04-27, 1404/02/07**

Update count: **0**

Registration date

2025-04-27, 1404/02/07

Registrant information

Name

Maryam Shafiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 2767

Email address

m_shafiee@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Streptococcus thermophilus, Lactiplantibacillus plantarum and the combination of these two probiotics on uremic pruritus in patients undergoing hemodialysis : A double-blind randomized clinical trial

Public title

Investigating the effect of probiotic supplements on uremic pruritus in patients undergoing hemodialysis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Continuous hemodialysis for more than three months They should have suffered from itching for at least 6 weeks.

Exclusion criteria:

Liver disease History of seizures Skin disease associated with itching Hemolytic blood disease First complaint of itching Use of any type of antibiotic Participation in another clinical trial in the past month pregnancy active cancer Active infection Sensitivity to probiotic compounds

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, block randomization will be conducted. Grouping of patients will be carried out in a double-blind manner. The drugs and placebo will be provided to the dialysis unit nurse in similar packaging (labeled with numbers one to four) based on block randomization, and they will not be aware of the contents of the packages. Based on the numbers and the patient list, they will distribute the drugs and placebo among the patients, who will also be unaware of the contents of the packages. On the other hand, data collection will be performed by another

researcher who has not been involved in the patient allocation process from the beginning and is unaware of it.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants (the form of the drug in the control group and the three intervention groups are selected to be completely identical in terms of appearance and method of consumption), nurses in the dialysis unit who distribute the medication, a researcher who completes the questionnaires, a researcher who collects data related to patients such as information related to the dialysis records of patients, a researcher who conducts the tests.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shiraz university of medical science

Street address

Shiraz, Zand Street, opposite Palestine Street, Central Building of Shiraz University of Medical Sciences.

City

Shiraz

Province

Fars

Postal code

71348-14333

Approval date

2025-03-15, 1403/12/25

Ethics committee reference number

IR.SUMS.MED.REC.1403.816

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

chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

2**Description of health condition studied**

uremic pruritus

ICD-10 code

ICD-10 code description

Pruritus, unspecified

Primary outcomes**1****Description**

uremic pruritus(method of Scale Analogue Visual and the Persian version of the 5-Scale Itching Questionnaire)

Timepoint

At the beginning of the study (before the intervention starts), during the intervention (6 weeks after the intervention starts), and after the intervention (immediately after 12 weeks from the start of the intervention).

Method of measurement

To assess itching, the Scale Analogue Visual method and the Persian version of the 5-Scale Itching Questionnaire, whose validity and reliability have been confirmed by Yousef Nejad, will be used

Secondary outcomes**1****Description**

C-REACTIVE PROTEIN

Timepoint

At the beginning of the study (before the intervention starts) and at the end of the intervention (after completing 12 weeks).

Method of measurement

ELISA

2**Description**

Interlukine-6

Timepoint

At the beginning of the study (before the intervention starts) and at the end of the intervention (after completing 12 weeks).

Method of measurement

ELISA

Intervention groups**1****Description**

Intervention group:Lactiplantibacillus plantarum group: Oral medication in the form of drops equivalent to CFU=1*10⁹ of Lactiplantibacillus plantarum bacteria administered daily for 12 weeks.Probiotics are prepared by Pardis Roshd Company under the supervision of a food industry specialist.

Category

Treatment - Drugs

2**Description**

Intervention group: Thermophilous Streptococcus group: Oral medication in the form of drops equivalent to CFU=1*10⁹ of Thermophilous Streptococcus bacteria administered daily for 12 weeks. Probiotics are prepared by Pardis Roshd Company under the supervision of a food industry specialist.

Category

Treatment - Devices

3**Description**

Intervention group:Oral medication in the form of drops equivalent to CFU=28 10⁹ evenly from Lactiplantibacillus plantarum and Thermophilous Streptococcus bacteria administered daily for 12 weeks. Probiotics are prepared by Pardis Roshd Company under the supervision of a food industry specialist.

Category

Treatment - Drugs

4**Description**

Control group: Oral medication in the form of drops (placebo) with maltodextrin administered daily for 12 weeks. Prepared by Pardis Roshd Company under the supervision of a food industry specialist.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi Hospital

Full name of responsible person

Maryam Shafiee

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Namazi Square, Zand Street, Namazi Hospital, Iran.

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Web page address<https://namazi.sums.ac.ir/>**Sponsors / Funding sources**

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadi Hamid

Street address

opposite Palestine Street, Zand Stree, Central
Building of Shiraz University of Medical Sciences,
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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

Mahboobe Rastgoo

Position

subspeciality assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Name of organization / entity

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Full name of responsible person

Mahboobe Rastgoo

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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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 further 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