Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 interlukine-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)

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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

L29.9

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

Street address

Namazi Square, Zand Street, Namazi Hospital, Iran.

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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, Shiraz

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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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Person responsible for scientific inquiries

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Full name of responsible person
Mahboobe Rastgoo

Position
subspeciality assistant

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Person responsible for updating data

Contact

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Position
subspeciality assistant

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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