# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)
**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**

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.

**City**

Shiraz

**Province**

Fars

**Postal code**

7193613311

**Phone**

+98 71 3612 5000

**Fax**

+98 71 3647 4326

**Email**

nemazee_inf@sums.ac.ir

**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, Shiraz

**City**
Shiraz

**Province**
Fars

**Postal code**
7134814336

**Phone**
+98 71 3230 5410

**Email**
Info@sums.ac.ir

**Web page address**
https://sums.ac.ir/

**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

**Street address**
No.243, Substreet 26.3, West Saheli, Shiraz.

**City**
Shiraz

**Province**
Fars

**Postal code**
7143618995

**Phone**
+98 71 3225 3578

**Email**
mahboob.rastgoo@gmail.com

## Person responsible for scientific 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

**Street address**
No.243, Substreet 26.3, West Saheli, Shiraz.

**City**
Shiraz

**Province**
Fars

**Postal code**
7143618995

**Phone**
+98 71 3225 3578

**Email**
mahboob.rastgoo@gmail.com

## Person responsible for updating data

**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

**Street address**
No.243, Substreet 26.3, West Saheli, Shiraz.

**City**
Shiraz

**Province**
Fars

**Postal code**
7143618995

**Phone**
+98 71 3225 3578

**Email**
mahboob.rastgoo@gmail.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 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