Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of synbiotic on severity uremic pruritus and muscle cramps in patients undergoing hemodialysis

Protocol summary

Study aim
To determine the effect of synbiotics on the severity of uremic pruritus and muscle cramps in patients undergoing hemodialysis

Design
Clinical Trial, by using block randomization, the Patients enter an intervention or control group, A pilot study including 30 patients from each group, will determine the size of the sample, Parallel groups, triple-blind.

Settings and conduct
This study is being conducted in the hemodialysis ward of Kowsar Hospital, Semnan. The medication is provided to the patient by the head nurse. In this way, the patient, researcher, and data analyst are not aware of the type of intervention and do not know who is in which group.

Participants/Inclusion and exclusion criteria
Consent and interest in participating, in the study Age 18 - 65 years old, Hemodialysis treatment at least twice a week for a maximum of four hours each time, Undergoing hemodialysis treatment for at least six months, Presence of uremic pruritus as diagnosed by a doctor for at least six months and obtaining a score of at least mild on the YOSIPOVITCH questionnaire, Experiencing muscle cramps at least once a week, Life expectancy and survival for at least three months

Intervention groups
The intervention group will consume two synbiotic capsules with the brand name Lactocare (500 mg) daily, one after lunch and the other after dinner, for eight weeks.

Main outcome variables
uremic pruritus severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250117064406N2**
Registration date: **2025-12-19, 1404/09/28**
Registration timing: **prospective**

Last update: **2025-12-19, 1404/09/28**
Update count: **0**

Registration date
2025-12-19, 1404/09/28

Registrant information

Name
Shahein Momenabadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-30, 1404/11/10

Expected recruitment end date
2026-07-01, 1405/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of synbiotic on severity uremic pruritus and muscle cramps in patients undergoing hemodialysis

Public title
Effect of synbiotic on severity uremic pruritus and muscle cramps in patients undergoing hemodialysis

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Consent and interest in participating in the study Age 18 - 65 years old Hemodialysis treatment at least twice a week for a maximum of four hours each time Undergoing hemodialysis treatment for at least six months Presence of uremic pruritus as diagnosed by a doctor for at least six months and obtaining a score of at least mild on the YOSIPOVITCH questionnaire Experiencing muscle cramps at least once a week Life expectancy and survival for at least three months
Exclusion criteria:
Kidney and organ transplant candidates Consuming synbiotics, probiotics, prebiotics, or antibiotics four weeks before participating in the study Having a severe infection within four weeks before study participation Chronic liver disease (hepatitis B, hepatitis C), pulmonary, cardiovascular, acute pancreatitis, gastrointestinal disorders (inflammatory bowel disease, ulcerative colitis, Crohn's, celiac disease, lactose intolerance or allergy, irritable bowel syndrome), active cancers, immunodeficiency, HIV
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The research sample was assigned to the study groups by permuted groups. After randomly selecting one of the two possible blocks, two consecutive samples are randomly placed in the intervention or control group. Blocking is used within gender and age. Regarding age, the first patient is randomly placed in the intervention or control group, and the next patient with a maximum age difference of five years is placed in another group. If the next patient's age difference is more than five years, the patient is randomly placed in another age block. Regarding gender, randomization is done separately for men and women. In other words, the first female patient is randomly placed in the intervention or control group and the next female patient is placed in another group, for the male patient's division is done in the same way.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The blinding of the drug is provided to the patient by the head nurse. In this way, the patient, the researcher, and the data analyst in the study did not know about the intervention type and did not know who was in which group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Boulevard, Semnan
City
Semnan
Province
Semnan
Postal code
3513138111
Approval date
2025-10-20, 1404/07/28
Ethics committee reference number
IR.SEMUMS.REC.1404.198

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Uremic pruritus severity
Timepoint
The severity of uremic pruritus will be measured before and after the intervention.
Method of measurement
YOSIPOVITCH Itch Questionnaire

Secondary outcomes

1

Description
Muscle cramps
Timepoint
Muscle cramps will be measured before and after the intervention.
Method of measurement
Visual analog scale

Intervention groups

1

Description
Intervention group: The intervention group will consume two synbiotic capsules with the brand name Lactocare (500 mg) daily, one after lunch and the other after dinner, for eight weeks.
Category
Treatment - Other

2

Description
Control group: The control group will consume two placebo capsules (containing 500 mg of cornstarch) daily, one after lunch and one after dinner, for eight weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Shahin Momenabadi
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Faculty of Nursing and Midwifery, Semnan University of Medical Sciences, Semnan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Semnan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Shahein Momenabadi
Position
Assistant Professor
Latest degree
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Physiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available