

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

recruiting

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

Semnan University of Medical Sciences

Full name of responsible person

Majid Eslami

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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

Ph.D.

Other areas of specialty/work

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