Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of paroxetine and serteraline in pruritus in esrd patients under hemodialysis

Protocol summary

Study aim

Determination and comparison of serum phosphorus, serum calcium, serum PTH, serum sodium, serum potassium, serum creatinine, blood urea, serum albumin, serum triglycerides, ALT, AST, complete blood count and total bilirubin levels in two groups treated with paroxetine and sertraline. Determination and comparison of pruritus in ESRD patients undergoing hemodialysis in two groups treated with paroxetine and sertraline.

Design

A phase 2, randomized, controlled clinical trial with parallel-group design, conducted on 62 patients. A random number table was used for randomization.

Settings and conduct

This randomized clinical trial will be conducted on 62 hemodialysis patients at Hajar Hospital. Using a random number table, participants will be randomly allocated into two groups: Group A: paroxetine 10 mg during the first week and 20 mg during the second to fourth weeks, and Group B: sertraline 25 mg during the first week and 50 mg during the following three weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent of the patient to participate in the study, Ages 18 to 80 years, ESRD patients with mild, moderate, or severe pruritus, No alcohol consumption, At least four weeks after diagnosis Exclusion criteria: Use of other antipruritic medications, history of skin diseases that may cause pruritus and not related to uremic pruritus, thyroid disease, liver disease, systemic lupus erythematosus, parathyroid hormone (PTH) > 450 pg/ml

Intervention groups

Group A : paroxetine 10 mg for the first week, 20 mg for the second, third and fourth weeks. Group B: sertraline 25 mg for the first week and 50 mg for the remaining three weeks.

Main outcome variables

Serum phosphorus, serum calcium, serum PTH, serum sodium, serum potassium, serum creatinine, blood urea, serum albumin, serum triglycerides, ALT, AST, complete blood count and total bilirubin, and itching level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251101067848N1**
Registration date: **2025-11-11, 1404/08/20**
Registration timing: **prospective**

Last update: **2025-11-11, 1404/08/20**
Update count: **0**

Registration date

2025-11-11, 1404/08/20

Registrant information

Name

Mahdis Azimipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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mahdisazimipour74@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-21, 1404/09/30

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of paroxetine and serteraline in pruritus in esrd patients under hemodialysis

Public title
Comparison of the effects of paroxetine and sertraline on pruritus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent of the patient to participate in the study Ages 18 to 80 years ESRD patients with mild, moderate, or severe pruritus who have been regularly undergoing long-term hemodialysis (three times per week, 4-hour HD sessions for more than 30 days) No alcohol consumption At least four weeks after diagnosis

Exclusion criteria:
Taking other anti-itch medications History of skin conditions that may cause itching and are not related to uremic pruritus Peripheral neuropathy Thyroid disease, leukemia, lymphoma, liver disease, systemic lupus erythematosus Parathyroid hormone (PTH) > 450 pg/ml

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, in order to allocate patients to two groups (First intervention and Second intervention), a randomization method using a random number table is used. Thus, a list of 62 patients eligible for the study is prepared and each patient is assigned a number from 1 to 62. Then, using a random number table, a random number is selected for each number. Odd numbers are assigned to First intervention group and even numbers to Second intervention group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Faculty of Medicine, Shahrekord University of Medical Sciences

Street address
University Headquarters, Kashani Blvd, Shahrekord

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Approval date
2025-08-02, 1404/05/11

Ethics committee reference number
IR.SKUMS.MED.REC.1404.076

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Mean phosphorus and calcium levels

Timepoint
After the intervention

Method of measurement
Laboratory

2

Description
Mean sodium and potassium levels

Timepoint
After the intervention

Method of measurement
Laboratory

3

Description
Mean Creatinine and urea levels

Timepoint
After the intervention

Method of measurement
Laboratory

4

Description
Mean Aspartate Aminotransferase and Alanine Aminotransferase levels
Timepoint
After the intervention
Method of measurement
Laboratory

5

Description
Mean Parathyroid hormone levels
Timepoint
After the intervention
Method of measurement
Laboratory

6

Description
Mean Albumin level
Timepoint
After the intervention
Method of measurement
Laboratory

7

Description
Mean Triglyceride levels
Timepoint
After the intervention
Method of measurement
Laboratory

8

Description
Mean Total bilirubin level
Timepoint
After the intervention
Method of measurement
Laboratory

9

Description
pruritus score on the 5-D itch scale
Timepoint
Before the intervention and then the third and fourth weeks after the intervention
Method of measurement
5-D itch scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: paroxetine 10 mg for the first week, 20 mg for the second, third and fourth weeks
Category
Treatment - Drugs

2

Description
Second intervention group: sertraline 25 mg for the first week and 50 mg for the remaining three weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital
Full name of responsible person
Mahdis Azimipour
Street address
Hajar Hospital, Parsart Ave, Shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. Akbar Soleiman
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University Headquarters, Kashani Blvd
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dr.akbarsoleymani@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Parisa Javadian
Position
Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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