

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of paroxetine and sertraline 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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Recruitment status

Recruitment complete

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 sertraline 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

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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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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**Contact****Name of organization / entity**

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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