Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect of Doxepin and Gabapentin in the Management of Uremic Pruritus in Hemodialysis Patients

Protocol summary

Study aim
Comparison of the effects of doxepin and gabapentin in the treatment of uremic pruritus in hemodialysis patients

Design
This clinical trial study was a controlled, parallel-group, unblinded, and randomized (sealed envelope) study. The study was conducted on 150 hemodialysis patients with uremic pruritus symptoms at Shahid Mohammadi Hospital in Bandar Abbas. The sealed envelope method was used for randomization.

Settings and conduct
This study will be conducted on 150 hemodialysis patients at Shahid Mohammadi Hospital in Bandar Abbas, and eligible patients will be randomly assigned to two intervention groups (gabapentin) and a control group (doxepin). The severity of itching and its impact on quality of life will be assessed at baseline and at weeks 1, 2, and 4 after treatment using the Visual Analogue Scale (VAS) and the 5-D Itch Scale.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Diagnosis of End-Stage Renal Disease (ESRD); Hospitalization and undergoing hemodialysis; Willingness to participate in the study Exclusion Criteria: Hepatic failure, hyperthyroidism, angle-closure glaucoma, heart block, decompensated heart failure, hypotension; History of hypersensitivity to gabapentin or doxepin; Uncontrolled psychiatric disorders, severe depression, or suicidal ideation; Myocardial infarction within the past three months; Epilepsy or any history of seizure, pregnancy; Skin conditions that could explain pruritus (psoriasis, atopic dermatitis, etc.); Gabapentin contraindications, doxepin contraindications

Intervention groups
Intervention group: 75 hemodialysis patients with pruritus symptoms and eligible for inclusion who receive a dose of gabapentin 300 mg. Control group 2: 75 hemodialysis patients with pruritus symptoms and eligible for inclusion who receive a dose of doxepin 10 mg.

Main outcome variables
Pruritus Severity: Impact of Pruritus on Quality of Life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250507065634N5**
Registration date: **2025-10-06, 1404/07/14**
Registration timing: **prospective**

Last update: **2025-10-06, 1404/07/14**
Update count: **0**

Registration date
2025-10-06, 1404/07/14

Registrant information
Name
mahnaz shafaei fallah
Name of organization / entity
Country
Iran (Islamic Republic of)
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articlelab.com@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-10-23, 1404/08/01
Expected recruitment end date
2025-12-01, 1404/09/10
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effect of Doxepin and Gabapentin in the Management of Uremic Pruritus in Hemodialysis Patients

Public title
The Effect of Doxepin and Gabapentin in the Management of Uremic Pruritus

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of End-Stage Renal Disease (ESRD) Hospitalization and undergoing hemodialysis Willingness to participate in the study (informed consent)

Exclusion criteria:
Patients with hepatic failure Hyperthyroidism Angle-closure glaucoma Heart block Decompensated heart failure Hypotension History of hypersensitivity to gabapentin or doxepin Uncontrolled psychiatric disorders Myocardial infarction within the past three months Epilepsy, history of even a single seizure, or pregnancy Patients with psoriasis, atopic dermatitis, or any other condition that could explain pruritus Contraindications to Gabapentin include: Renal impairment; Psychiatric or mood disorders such as depression and suicidal ideation; Substance or alcohol abuse; Respiratory disorders. Contraindications to Doxepin: Bleeding disorders; Recent myocardial infarction; Urinary disorders such as prostatic hypertrophy; Personal or family history of angle-closure glaucoma; Personal or family history of psychiatric or mood disorders (e.g., bipolar disorder, psychosis); Family history of suicide; Seizures or conditions that may increase the risk of seizures (e.g., other brain disorders, alcohol/sedative withdrawal).

Age
From **16 years** old to **80 years** old

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Experimental and control groups: After selecting the sample, in the next step, people are divided into experimental and control groups using a random method. How to perform randomization: First step: After selecting the voluntary sample, all selected people are placed on a list (numbers from one to 150 are assigned to people). Second step: From these people, using a random method using sealed and opaque (numbered) envelopes, people are divided into experimental and control groups. Each person randomly selects an envelope and is divided into the corresponding 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
Research Ethics Committees of Hormozgan University of Medical Sciences

Street address
Deputy of research and technology, campus of Hormozgan University of Medical Sciences, Imam Hossein boulevard, Bandar Abas, Iran

City
BandarAbas

Province
Hormozgan

Postal code
7919692004

Approval date
2025-08-27, 1404/06/05

Ethics committee reference number
IR.HUMS.REC.1403.220

Health conditions studied

1

Description of health condition studied
Uremic Pruritus

ICD-10 code
L29.8

ICD-10 code description
Other pruritus

Primary outcomes

1

Description
Pruritus Severity

Timepoint
Before the intervention and after 1 week, 2 weeks and 4 weeks after the intervention

Method of measurement
Using the Visual Analogue Scale

2

Description

Impact of Pruritus on Quality of Life

Timepoint

Before the intervention and after 1 week, 2 weeks and 4 weeks after the intervention

Method of measurement

Using the 5-D Itch Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 75 hemodialysis patients of Shahid Mohammadi Hospital, Bandar Abbas, who suffer from Pruritus and meet the inclusion criteria, will be randomly assigned to the study as the intervention group. This group will receive gabapentin. The starting dose of gabapentin will be 300 mg (Sobhan Daru Company) every other night after each dialysis session. In cases where inadequate response is defined as a decrease of less than 2 units in the visual analog scale (VAS) score after one week of treatment, the gabapentin dose will be increased to 300 mg per day. The severity of Pruritus and its impact on quality of life will be assessed at baseline and after 1 week, 2 weeks, and 4 weeks after the intervention, respectively, using the visual analog scale and the D-5 itching scale.

Category

Diagnosis

2

Description

Control group: 75 hemodialysis patients of Shahid Mohammadi Hospital, Bandar Abbas, who suffer from Pruritus and meet the inclusion criteria, will be randomly assigned to participate in the study as the intervention group. This group will receive doxepin. The starting dose of doxepin will be 10 mg (Ramofarin Company) every night after each dialysis session. In cases where an inadequate response is defined as a decrease of less than 2 points in the visual analog scale (VAS) score after one week of treatment, the dose of doxepin will be increased to 10 mg twice a day. The severity of Pruritus and its impact on quality of life will be assessed at baseline and after 1 week, 2 weeks, and 4 weeks after the intervention, respectively, using the visual analog scale and the D-5 itching scale.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital, Bandar Abbas

Full name of responsible person

Ehsan Ramezanian Nik

Street address

Shahid Mohammadi Hospital, Eastern Wing, Payambar-e Azam Complex, Jomhouri Eslami Boulevard, Bandar Abbas, Hormozgan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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

Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
AmirAhmad Shojaei
Position
Medical student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data and the main outcome results of the research can be shared after de-identification and preserving the privacy of individuals.
When the data will become available and for how long
Data can be made available 4 months after the results are published and after personally identifiable information is removed.
To whom data/document is available
The study data and documentation will be available to researchers and scholars working at reputable academic and scientific institutions.
Under which criteria data/document could be used
Research data and documentation may be used for scientific and research purposes. Users must undertake to keep non-identifiable data confidential.
From where data/document is obtainable
If you need data, please contact Amirahmadshojaei76@gmail.com
What processes are involved for a request to access data/document
After receiving and reviewing the request from the researcher, the request will be responded to as soon as possible.
Comments