

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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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Email address

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

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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 Ramezani Nik

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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Other areas of specialty/work
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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