

# 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)

##### Phone

+98 915 930 0704

##### 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

**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 Ramezani Nik

#### Street address

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

#### City

Bandar Abbas

#### Province

Hormozgan

#### Postal code

7916613885

#### Phone

+98 76 3333 7611

#### Email

info@hums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Sharam Zare

##### Street address

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

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7919692004

##### Phone

+98 76 3128 1680

##### Email

research@hums.ac.ir

#### 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**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**Unit 36, 6th Floor, Khorshid Building, Goharan 20,  
Damahi Street, Bandar Abbas, Hormozgan, Iran**City**

Bandar Abas

**Province**

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**Postal code**

۷۹۱۵۳-۱۵۵۳۵

**Phone**

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**Email**

Amirahmadshojaei76@gmail.com

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**Unit 36, 6th Floor, Khorshid Building, Goharan 20,  
Damahi Street, Bandar Abbas, Hormozgan, Iran**City**

Medical student

**Province**

Hormozgan

**Postal code**

۷۹۱۵۳-۱۵۵۳۵

**Phone**

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**Email**

Amirahmadshojaei76@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Maryam Farokh Shahi

**Position**Assistant Professor of Dermatology, Hormozgan  
University of Medical Sciences**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**Payambar-e Azam Educational and Therapeutic  
Complex, Opposite District 3 Municipality, Jomhour  
Eslami Boulevard, Bandar Abbas, Hormozgan, Iran**City**

Bandar Abas

**Province**

Hormozgan

**Postal code**

15519-79199

**Phone**

+98 914 032 7395

**Email**

dr.maryamfarokhshahii@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

AmirAhmad Shojaei

**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**