Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Study of the effect of 6 % Gabapentin topical cream on uremic pruritus in maintenance hemodialysis patients a randomized double-blind placebo controlled clinical trial

Protocol summary

Study aim
Investigating the effect of 6% Gabapentin topical cream on uremic pruritus in chronic hemodialysis patients

Design
The clinical trial has a control group, with parallel groups, double-blind, randomized, on 68 patients. Randomization is done with https://www.sealedenvelope.com.

Settings and conduct
The study will be conducted at Razi Hospital in Rasht. The study will be conducted in two intervention and control groups. Participants and researchers will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients over 18 years of age undergoing hemodialysis treatment (at least 2 times a week and for at least 8 weeks) who scored higher than 5 on the 11-point VAS scale, were included in the study after obtaining informed consent. Exclusion criteria: patients who have been treated with antihistamines and emollients, patient sensitivity to gabapentin or placebo, pregnancy, breastfeeding.

Intervention groups
Each patient is given a jar for 30 days. Group A receives gabapentin cream and group B receives placebo. Then the patients are asked to use 2 grams of the cream on the itchy area at night.

Main outcome variables
Duration of itching throughout the day, intensity of itching, quality of sleep, quality of social relationships, quality of presence at work or home or school and the number of areas affected by itching.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20220516054879N8**
Registration date: **2023-11-04, 1402/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-04, 1402/08/13**
Update count: **0**

Registration date
2023-11-04, 1402/08/13

Registrant information
Name
maryam shahrokhi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3336 9026
Email address
mshahrokhi@gums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-10-20, 1402/07/28
Expected recruitment end date
2024-04-16, 1403/01/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of 6 % Gabapentin topical cream on uremic pruritus in maintenance hemodialysis patients a randomized double-blind placebo controlled clinical trial

Public title
Effects of topical Gabapentin 6% cream and placebo on uremic pruritus in hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old who are undergoing hemodialysis treatment (at least 2 times a week and for at least 8 weeks). Patients who scored higher than 5 in the 11-point VAS scale. Obtaining informed consent
Exclusion criteria:
Patients who have been treated with antihistamines and emollients. Patient sensitivity to gabapentin or placebo Pregnancy Breastfeeding
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be entered into each of the 2 drug (A) and placebo (B) treatment groups using the block randomization method with a ratio of 1:1. Randomization will be done in such a way that each patient will be assigned number 1 to 68. Then a table that has 17 rows called blocks and each block will have 4 parts and each part will be named A and B will be considered. In the next step, the numbers are placed in each house in order. After all the numbers are placed in the blocks, the people who have numbers in house A will receive the drug and the people who have numbers in house B will receive placebo. The website https://www.sealedenvelope.com is used for randomization. For allocation concealment, opaque-sealed envelopes will be used.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind study. The type of treatment will be placed inside a sealed envelope and delivered to the nurse and statistical analyst. The researcher and the participant will be blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Deputy of research and technology, In front of 17 shahrivar hospital, Shaid siadati street,Namjoo street, Rasht
City
Rasht
Province
Guilan
Postal code
4193713111
Approval date
2023-10-18, 1402/07/26
Ethics committee reference number
IR.GUMS.REC.1402.374

Health conditions studied

1

Description of health condition studied
Uremic pruritus
ICD-10 code
L29.9
ICD-10 code description
Pruritus, unspecified

Primary outcomes

1

Description
Duration of itching during the day and night
Timepoint
The duration of itching during the day and night is measured at the beginning of the study and then in the second and fourth weeks.
Method of measurement
Based on questions from the patient using the 5D-itch questionnaire

2

Description
Intensity of itching
Timepoint
The intensity of itching is measured at the beginning of the study and then in the second and fourth weeks.
Method of measurement
Based on questions from the patient using the 5D-itch questionnaire

3

Description

sleep quality

Timepoint

The effect of itching on sleep quality is measured at the beginning of the study and then in the second and fourth weeks.

Method of measurement

Based on questions from the patient using the 5D-itch questionnaire

4

Description

Quality of social relationships

Timepoint

The effect of itching on the quality of social relationships is measured at the beginning of the study and then in the second and fourth weeks.

Method of measurement

Based on questions from the patient using the 5D-itch questionnaire

5

Description

Quality of presence at work or home

Timepoint

The effect of itching on the quality of being at work or at home is measured at the beginning of the study and then in the second and fourth weeks.

Method of measurement

Based on questions from the patient using the 5D-itch questionnaire

6

Description

The number of areas affected by itching

Timepoint

The effect of the number of areas affected by itching is measured at the beginning of the study and then in the second and fourth weeks.

Method of measurement

Based on questions from the patient using the 5D-itch questionnaire

Secondary outcomes

1

Description

General condition of uremic itching in patients during one month

Timepoint

The general condition of uremic itching of patients is measured at the beginning of the treatment and then in the second and fourth weeks.

Method of measurement

Based on asking the patient using the VAS scale

Intervention groups

1

Description

Intervention group: Receiving a 6% gabapentin topical cream once a day for 1 month

Category

Treatment - Drugs

2

Description

Control group: Receiving a placebo (cold cream) once a day for 1 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Maryam Shahrokhi

Street address

Modafean Salamat Blvd, Razi Educational Remedial & Research Center

City

Rasht

Province

Guilan

Postal code

41448 95655

Phone

+98 13 3355 0028

Email

razi.hospital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

محمدرضا نقی پور

Street address

In front of 17 shahrivar Hospital, Shahid Siadati Street, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4193713111

Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Maryam Shahrokhi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
17shahrivar Hospital, Shahid Siadati Street, Namjoo Street

City
Rasht

Province
Guilan

Postal code
4144654379

Phone
+98 13 3336 9019

Email
shahrokhi.mail85@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Maryam Shahrokhi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
17shahrivar Hospital, Shahid Siadati Street, Namjoo Street

City
Rasht

Province
Guilan

Postal code
4144654379

Phone
+98 13 3336 9019

Email
shahrokhi.mail85@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Sabah Sadat Moraghebi

Position
Pharmacy Student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Unit 4, No.1174, Yousefi Alley, Namjoo Street

City
Rasht

Province
Guilan

Postal code
4144664145

Phone
+98 901 303 9671

Email
sabah.moraghebi1377@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Patient privacy and ethical principles

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
The results of the study will be available to everyone, specific information will be available only to the treatment staff. To protect the patient's privacy, the patient's information will be protected by the researcher.

When the data will become available and for how long

There is currently no plan to publish the data, but if published, it will be 6 months after the results are published.

To whom data/document is available

Researchers who are active in this field - Nerphrologists and scientific and qualified people

Under which criteria data/document could be used

Physicians and researchers will have the right to request, there are restrictions on patient privacy and medical ethics

From where data/document is obtainable

Dr. Maryam Shahrokhi, razi Hospital, Rasht; Sabah Sadat Moraghebi School of Pharmacy guilan university of meical science

What processes are involved for a request to access data/document

Refer to the razi Hospital in Rasht and sign the application form, then meet with the project researcher and review the client's request - consult with the Medical Ethics Committee, then provide documentation

Comments