Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of gabapentin topical cream in improving itching of end-stage renal disease to dialysis

Protocol summary

Study aim
Determining the effectiveness of gabapentin topical cream in improving itching in dialysis patients

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 80 patients. We use a table of random numbers for randomization.

Settings and conduct
Patients of Al-Zahra, Khorshid and Amin dialysis centers who have the conditions to enter the study are randomly divided into 2 groups. To randomize the samples, we use the table of random numbers. The creams prepared in this study are named into two groups No. 1 and 2, one of which is Gabapentin topical cream and the other is placebo, which includes the cream base. Unaware to observe the three-blindness of the study.

Participants/Inclusion and exclusion criteria
Target community patients with pruritus ani. The itching studied in this study should be itching of the whole body except the head, face and neck.

Intervention groups
One group is given cream number 1 and the other group is given cream number 2. Patients receive the creams for 4 weeks. The dose is used once a day for itchy areas of the body, but more than 50 grams per week (equivalent to one tube) should not be used and will be followed for 4 weeks after that.

Main outcome variables
Determining the mean changes in pruritus score before and after application of gabapentin topical cream according to age, sex, duration of dialysis initiation and underlying cause of dialysis. The possible skin complication of topical gabapentin cream is also examined.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220306054206N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**

Registration date
2022-03-17, 1400/12/26

Registrant information

Name
Parisa Mohamadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-20, 1401/02/30

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of gabapentin topical cream in improving itching of end-stage renal disease to dialysis

Public title

The effect of gapentin cream on pruritus in dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Target community patients with pruritus ani. The itching studied in this study should be itching of the whole body except the head, face and neck.

Exclusion criteria:

Itching of the head, neck and face Other simultaneous skin diseases on the trunk and limbs

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the samples, we use the table of random numbers. For this purpose, we give a number to each person who has a dialysis file, and then, based on the random number table, the first 40 numbers of drug number 1 and the next 40 numbers of drug number 2 are given.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The creams prepared in this study are named into two groups No. 1 and 2, one of which is Gabapentin topical cream and the other is placebo, which includes the cream base. Unaware to observe the three-blindness of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Azadi Square, Hezar Jerib St., School of Medicine - Isfahan University of Medical Sciences (Research Ethics Committee)

City

Esfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-02-19, 1400/11/30

Ethics committee reference number

IR.MUI.MED.REC.1400.808

Health conditions studied

1

Description of health condition studied

Itching end-stage renal disease leading to dialysis

ICD-10 code

L29

ICD-10 code description

Pruritus

Primary outcomes

1

Description

Determining the effectiveness of gabapentin topical cream in improving itching in dialysis patients

Timepoint

Patients receive medication for 4 weeks and are followed up for 4 weeks thereafter

Method of measurement

Two questionnaires are used to score patients' pruritus: 12-item and 5-item

Secondary outcomes

1

Description

Determining the mean changes in pruritus score before and after application of Gabapentin topical cream according to age and sex, duration of dialysis initiation and underlying cause of dialysis

Timepoint

Patients receive medication for 4 weeks and are followed up for 4 weeks thereafter

Method of measurement

By two questionnaires: 12-item and 5-item

Intervention groups

1

Description

Intervention group: Gabapentin will be dissolved in the liquid phase, and finally 5% gabapentin cream will be prepared in water-based cold cream type oil. It is used once a day for 4 weeks on itchy areas, but do not consume more than 50 grams per week.

Category

Treatment - Drugs

2

Description

Control group: The drugs in this group can be used as a cream-based placebo. It can be taken once a day on itchy areas, but it should not be taken more than 50 grams per week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

مَرکز دیالیز الزهرا ,خورشید و امین

Full name of responsible person

Parisa Mohammadian

Street address

Hakim Nezami Three Ways, Shohada Sofeh Street, Al-Zahra Hospital. Khorshid Hospital Governorate Street. Ibn Sina St. Amin Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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Azadi Square, Hezar Jarib St., Isfahan University of Medical Sciences, Vice Chancellor for Research and Technology

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parisa Mohamadian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person

Gita Faghihi

Position

Professor

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Specialist

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

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

Statistical data are generally shared. In other words, each person's data is not displayed alone, but their overall results and averages are shared with the statistical analysis method.

When the data will become available and for how long

Data access time 3 months after printing the results

To whom data/document is available

Any researcher can apply for data

Under which criteria data/document could be used

They can access the data if similar research is underway and they submit evidence of the study.

From where data/document is obtainable

Via email parisa14m@yahoo.com to Parisa Mohammadian

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

They will have access to the data within a maximum of one month after sending the documents stating that the following project has been completed

Comments