

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of topical piroxicam in the treatment of uremic pruritus: A randomized double-blinded placebo control clinical trial

Protocol summary

Study aim

Determining the effect of topical piroxicam on uremic pruritus in hemodialysis patients

Design

A clinical trial with a control group, with a parallel-group, double-blind, randomized, phase 3 on 50 patients, the table of random numbers obtained from the RAND function of Excel software is used for randomization.

Settings and conduct

Study place: Shahid Rahnamon Hospital, Yazd. Patients who meet the inclusion criteria are placed in one of the two treatment groups with piroxicam gel (group A) or basic gel (group B). Randomization is done based on the RAND() function of Excel software. Based on this, a table of random numbers is prepared, and the patients are placed in groups A or B according to the rows of this table and receive the product related to their group. the numbered Gels will be available to the attending physician and them. Patients are evaluated on days 1, 7 and 14.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-70 years; suffering from uremic pruritus with localized uremic pruritus; without a history of piroxicam allergy; not pregnant or breastfeeding. Exclusion criteria: aggravation of the disease; not taking the medicine for more than two days in a row; causing unwanted side effects from the medicine; unwillingness of the participant to continue cooperation.

Intervention groups

Intervention group: treatment with 0.5% piroxicam gel, once a day, topical application for up to 2 weeks. Control group: treatment with placebo gel (lubricant gel), once a day, topical application for up to 2 weeks.

Main outcome variables

Pruritus score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N18**

Registration date: **2023-07-25, 1402/05/03**

Registration timing: **retrospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3820 3865

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mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical piroxicam in the treatment of uremic pruritus: A randomized double-blinded placebo control clinical trial	
Public title	The effect of topical piroxicam in the treatment of uremic pruritus
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients undergoing hemodialysis more than 3 times a month Insensitivity to piroxicam Patients with chronic uremic pruritus Absence of pregnancy and breastfeeding Exclusion criteria: Patients with underlying skin disease Allergic to Piroxicam Pregnancy
Age	From 18 years old to 70 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Care provider
Sample size	Target sample size: 50
Randomization (investigator's opinion)	Randomized
Randomization description	Patients are randomly assigned to one of the two groups of piroxicam gel and placebo based on the RAND function of Excel software in the order of entry into the study.
Blinding (investigator's opinion)	Double blinded
Blinding description	The study will be done in a double-blind manner. Patients and doctors (therapist and evaluator) will not know about the intervention. Piroxicam gel and Base gel are numbered by one of the researchers who does not intervene in the study process (treatment, evaluation, and data analysis) with labels one and two, and only the same researcher knows about the numbering of worms. Then the numbered gels are delivered to the patients by the doctor.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	<u>1</u> Ethics committee Name of ethics committee Ethics committee of Shahid Sadoughi University of Medical Sciences Street address Alem sq. City Yazd Province Yazd Postal code 8916978477 Approval date 2023-06-26, 1402/04/05 Ethics committee reference number IR.SSU.MEDICINE.REC.1402.094
Health conditions studied	<u>1</u> Description of health condition studied Uremic pruritus ICD-10 code L29 ICD-10 code description Pruritus
Primary outcomes	<u>1</u> Description Uremic pruritus Timepoint ?Before intervention and 7, 14 days after intervention Method of measurement Pruritus questionnaire
Secondary outcomes	empty
Intervention groups	<u>1</u> Description Intervention group: 25 patients with uremic pruritus treated with 0.5% piroxicam gel (manufactured by a domestic pharmaceutical company), topical application, once a day for 14 days. Category Treatment - Drugs
<u>2</u>	Description Control group: 25 patients with uremic itching who were treated with base gel (lubricant gel made by a domestic

pharmaceutical company), topical application, once a day for 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahnemon Hospital

Full name of responsible person

Dr. Mahdi Zahmatkesh

Street address

Farokhi st.

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Yazd

Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice President of Research and Technology, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohsen Zabihi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available