

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Assessment of Antipruritic effect of Pimecrolimus Cream %1 in Patients with Chronic Renal Failure referring to Ahwaz Imam Khomeini Hospital-Iran dialysis center during 2009.

Protocol summary

Summary

The purpose of study was assessment of anti-pruritic effect of pimecrolimus cream %1 in patients with chronic renal failure. This study was conducted as a randomized double-blind, placebo control, single center and phase II trial. 60 known cases of chronic renal failure, between 18 and 60 years old and not using antihistaminic agents or other anti-pruritic drugs during last 3 months, without any other pruritic diseases were recruited. These patients selected from hospitalized chronic renal failure patients referred to Dialysis center of Ahwaz Imam Khomeini hospital. Placebo and main drug was utilized by patients in 8 weeks during 1 January and 1 April 2010. They were asked 9 times after starting the study, first at the baseline and then every week till eighth week, for pain and burning level due to lesions based on 0 to 10 (0 indicates no pain and burning and 10 indicates the worst pain that is conceivable for patients).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2010111015069N1**
Registration date: **2011-04-18, 1390/01/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-18, 1390/01/29

Registrant information

Name

Alireza Ghorbani Birgani

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Gachsaran Islamic Azad University

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2010-04-01, 1389/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Antipruritic effect of Pimecrolimus Cream %1 in Patients with Chronic Renal Failure referring to Ahwaz Imam Khomeini Hospital-Iran dialysis center during 2009.

Public title

Antipruritic effect of Pimecrolimus Cream %1 in Patients with Chronic Renal Failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known case of chronic renal failure, between 18 and 60 years old, not using of antihistamines or other anti-pruritus drugs during last 3 months.
Exclusion criteria: the presence of other known pruritic diseases.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University

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Academic Complex (Site)-Islamic Azad University

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Gachsaran

Postal code

32356

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

325

Health conditions studied**1****Description of health condition studied**

End stage renal disease

ICD-10 code

N 18.0

ICD-10 code description

بیماری کلیوی مراحل انتهایی

Primary outcomes**1****Description**

pruritus

Timepoint

before intervention and every week for eight weeks

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Pimecrolimus cream 1%, 30 gram twice a day for 8 weeks after dialysis in intervention group

Category

Treatment - Drugs

2**Description**

Placebo cream (Emolient), 30 garm for 8 weeks twice a day after dialysis in control group

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ahwaz Imam Khomeinie Hospital

Full name of responsible person

Alireza Ghorbani Birgani

Street address

Azadegan Ave-Imam Khomeinie Hospital

City

Ahwaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gachsaran Islamic Azad University

Full name of responsible person

Saman Moosavian

Street address

Academic Complex (Site)-Islamic Azad University

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Gachsaran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gachsaran Islamic Azad University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Gachsaran Islamic Azad University

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty