

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of cromolyn sodium gel 4% and pimecrolimus cream 1% anti pruritis effects on end stage renal failure patients undergoing dialysis in Ahwaz Imam Khomeini hospital in 2011

Protocol summary

Summary

The purpose of this study was to assess the response to treatment of cromolyn sodium gel 4% and comparison with pimecrolimus cream 1% in chronic renal patients. This study was conducted as a randomized double-blind, single center. 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. Drugs were utilized by patients in 8 weeks during 9 April and 9 June 2011. 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: **IRCT201107095069N3**
Registration date: **2011-07-15, 1390/04/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-15, 1390/04/24

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

2011-04-09, 1390/01/20

Expected recruitment end date

2011-06-09, 1390/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of cromolyn sodium gel 4% and pimecrolimus cream 1% anti pruritis effects on end stage renal failure patients undergoing dialysis in Ahwaz Imam Khomeini hospital in 2011

Public title

A comparative study of cromolyn sodium gel 4% and pimecrolimus cream 1% anti pruritis effects on end stage renal failure patients undergoing dialysis in Ahwaz Imam Khomeini hospital in 2011

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known case of chronic renal failure, aged 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

N/A

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**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Islamic Azad University

Street address

Academic Complex (Site)-Islamic Azad University

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Gachsaran

Postal code

32356

Approval date

2011-03-15, 1389/12/24

Ethics committee reference number

415

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

End stage renal disease

ICD-10 code

N 18.0

ICD-10 code description

End stage renal disease

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**

Cromolyn Sodium gel 4%, 40 gram twice a day for 8 weeks after dialysis in first intervention group

Category

Treatment - Drugs

2**Description**

Pimecrolimus cream 1%, 40 gram twice a day for 8 weeks after dialysis in second intervention 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
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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