

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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)

##### Phone

+98 61 1229 8173

##### Email address

ghorbani@iaug.ac.ir

##### 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

##### City

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

##### City

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**

Saman Moosavian

**Position**

Faculty Member/Master

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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*