

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Evaluating the Effect of Cromolyn Sodium in Uremic Pruritus

#### Protocol summary

##### Summary

Pruritus is a major disorder among the skin derangements in advanced renal failure. Cromolyn sodium is a mast cell stabilizing agent that inhibits degranulation of mast cells and the release of histamine, tryptase, and leukotrienes. It is hypothesized that oral cromolyn sodium may attenuate uremic pruritus by decreasing serum tryptase level. In this study we include 20 dialysis patients without pruritus as a negative control. Sixty hemodialysis patients > 18 yo suffering from pruritus for at least 6 weeks, and who have not responded to other drugs, willing and able to give informed consent will be included. A baseline blood sample will be taken to determine the plasma levels of tryptase. A baseline level of pruritus will also be determined for the 60 patients who were suffering from pruritus using the Visual Analogue scale (VAS). The 60 patients with pruritus are randomly assigned into 2 groups, and the study is double blind. Patients receive oral cromolyn sodium or placebo, 135mg, 3 times daily for 8 weeks. The level of pruritus will be determined 3 times a week during the whole study period. A second blood sample will be taken after 8 weeks to determine tryptase level. Next, the drug or placebo will be discontinued and the tryptase level rechecked after 4 weeks. All blood samples will be frozen at -70 C and sent to Tehran Asthma and Allergy center for tryptase determination via UNICAP.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138710291562N1**  
Registration date: **2009-06-23, 1388/04/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-06-23, 1388/04/02

##### Registrant information

###### Name

Ghazal Vessal

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1242 4127

###### Email address

gvessal@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz University of medical Sciences

##### Expected recruitment start date

2008-08-04, 1387/05/14

##### Expected recruitment end date

2009-01-04, 1387/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the Effect of Cromolyn Sodium in Uremic Pruritus

##### Public title

Evaluating the Effect of Cromolyn Sodium in Uremic Pruritus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Hemodialysis patients > 18 yo suffering from pruritus for at least 6 weeks, and who have not responded to other drugs Willing and able to

give informed consent Exclusion Criteria: Known dermatologic, liver, metabolic disease, or any other disease or condition other than ESRD that causes pruritus consumption of antihistamines or other antipruritic drugs Lactase deficiency

#### Age

From **18 years** old to **75 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

### 1

#### Registry name

clinicaltrials.gov

#### Secondary trial Id

NCT00745199

#### Registration date

2008-09-02, 1387/06/12

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Zand street- central building of Shiraz University of Medical Sciences, seventh floor

##### City

Shiraz

##### Postal code

71345

#### Approval date

2008-08-04, 1387/05/14

#### Ethics committee reference number

4146-87-ct

## Health conditions studied

### 1

#### Description of health condition studied

pruritus in dialysis patients

#### ICD-10 code

N28

#### ICD-10 code description

Other disorders of kidney and ureter, not elsewhere classified

## Primary outcomes

### 1

#### Description

pruritus

#### Timepoint

3 times a week up to 8 weeks

#### Method of measurement

VAS

## Secondary outcomes

### 1

#### Description

tryptase serum level

#### Timepoint

8 weeks

#### Method of measurement

UNICAP

## Intervention groups

### 1

#### Description

cromolyn sodium 135 mg TID for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

placebo in control group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nemazi Hospital

##### Full name of responsible person

##### Street address

##### City

Shiraz

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Faghihi Hospital

**Full name of responsible person**

**Street address**

**City**

Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of medical sciences

**Full name of responsible person**

Dr Mohammad Hossein Dabbaghmanesh

**Street address**

Vice chancellor for research, Shiraz University of medical Sciences

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

4146

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

Yes

**Title of funding source**

Shiraz University of medical sciences

**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**

Faculty of Pharmacy, Shiraz University of medical Sciences

**Full name of responsible person**

Dr.Ghazal Vessal

**Position**

Assistant prof

**Other areas of specialty/work**

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**Email**

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**Web page address**

**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*