Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 concent 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 randomely 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
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Iran (Islamic Republic of)
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+98 71 1242 4127
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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 concent 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
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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