Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparing the effects of Zinc sulfate and Hydroxyzine on pruritus of hemodialysis patients , a double blind randomized control trial

Protocol summary

Summary

The aim of this study was to compare the effect of zinc sulfat and Hydroxyzine in the treatment of pruritus in hemodialysis patients is ongoing. The study is double-blind clinical trial patients who consent to participate in the trial and that they have at least three months of hemodialysis and other anti-itch medication received and not sensitive to zinc sulfate and hydroxyapatite saddle and in the study has been kidney transplantation, Cherubis and increased alkaline phosphatase or intolerance to either of these two drugs are excluded. During a three-month study of 50 patients in the group with zinc sulfate tablets 220 mg of zinc daily (one tablet first month, two tablets in second month and three tablets in third month) and 50 patients in the control group, with hydroxyzine tablets 25 mg daily (one tablet first month, two tablets in second month and three tablets in third month) receive. Itching in 15 days to three months before and after the test was measured by VAS and compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411252954N5**
Registration date: **2015-11-26, 1394/09/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-26, 1394/09/05

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Ssciences and Health

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Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Zinc sulfate and Hydroxyzine on pruritus of hemodialysis patients , a double blind randomized control trial

Public title

Evaluation effects of Zinc sulfate and Hydroxyzine in pruritus treatment of hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic pruritus refractory to other treatments over 4 weeks. In the last 2 weeks in 1 month moisturizing cream and antihistamines to relieve itching liver. Patients have not used. Exclusion criteria: drug intolerance - a kidney transplant before the end of the study - Hyperparathyroidism - increased ALK, sensitivity to any of the above medications, Patient dissatisfaction

Age
From **15 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
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
Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences,7 Tir squer, Shahroud
City
Shahroud
Postal code
3616647555
Approval date
2015-09-07, 1394/06/16
Ethics committee reference number
IR.SHMU.REC.1394.73

Health conditions studied

1

Description of health condition studied
Pruritus of Hemodialysis patients
ICD-10 code
N18.0
ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
Severity Pruritus
Timepoint
Twice a weeks
Method of measurement
Visual Analog Scor(VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Group I) will receive Zinc sulfate. Zinc sulfate will be started as 220 mg/day for the firth month,440mg/day for second month and 660 mg/day for third month . pruritus will be checked every two week . Zinc sulfate will continue till 12 weeks.
Category
Treatment - Drugs

2

Description
Control group (Group II) will receive Hydroxyzine. Hydroxyzine will be started as 25 mg/day for the firth month,50 mg/day for second month and 75 mg/day for third month . pruritus will be checked every two week . Hydroxyzine will continue till 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital of Shahroud
Full name of responsible person
Dr.Monireh Amerian
Street address
Imam Hossein hospital, End Imam street , Shahroud , Iran
City
Shahroud

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahroud University medical and Sciences
Full name of responsible person
Dr. Mohammad Hasan Imamian
Street address
Vice chancellor for research, Shahroud University medical Sciences ,7th Tir squar, Shahroud

City
Shahroud
Grant name
بودجه پژوهشی
Grant code / Reference number
9423
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahroud University medical and 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
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Person responsible for updating data

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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