

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 5054

##### Email address

mb.sohrabi@shmu.ac.ir

##### 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**  
empty

**Type of organization providing the funding**  
empty

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**  
Shahroud University of Medical Sciences

**Full name of responsible person**  
Dr.Mohammad Bagher Sohrabi

**Position**  
General practitioner

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Dr.Monireh Amerian

**Position**

Nephrologist

**Other areas of specialty/work**

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## Person responsible for updating data

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Shahroud University of Medical science

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**Position**  
General Practitioner

**Other areas of specialty/work**

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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