Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of Gabapentin and Hydroxyzine in pruritus in dialysis patients

Protocol summary

Study aim

The objective of this randomized, double-blind clinical trial is evaluation of the effect of Gabapentin and Hydroxyzine in pruritus of dialysis patients.

Design

In this study, 30 dialysis patients with pruritus will be assigned into the study randomly and the subjects will be divided into two groups A and B randomly. Inclusion criteria of the study are dialysis patients and pruritus. Exclusion criteria of the study are Severe dry skin; Scabies; Psoriasis; Skin lymphoma; Liver cholestasis; Neurological patients and Psychologic patients.

Settings and conduct

In this randomized, double-blind clinical trial, 30 dialysis patients with pruritus will be assigned into the study randomly and the subjects will be divided into two groups A and B randomly. The Pruritus Scale questionnaire will be used to measure the Pruritus. Tablet Gabapentin 100mg oral, once in a day will be administered for six weeks for group (A) and Tablet Hydroxyzine 25mg oral, once in a day will be administered for six weeks for group (B). Patients will be evaluated after six weeks. Patients will not receive drugs for two weeks for pruritus. Then Tablet Gabapentin 100mg oral, once in a day will be administered for six weeks for group (B) and Tablet Hydroxyzine 25mg oral, once in a day will be administered for six weeks for group (A). Patients will be evaluated after six weeks again. Finally the collected data will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study are dialysis patients and pruritus. Exclusion criteria of the study are Severe dry skin; Scabies; Psoriasis; Skin lymphoma; Liver cholestasis; Neurological patients and Psychologic patients.

Intervention groups

Tablet Gabapentin 100mg oral, once in a day will be administered for six weeks for group (A) and Tablet Hydroxyzine 25mg oral, once in a day will be administered for six weeks for group (B).

Main outcome variables

The Pruritus Scale questionnaire will be used to measure the Pruritus at the beginning of the first intervention, 6 weeks after the first intervention, at the beginning of the second intervention and 6 weeks after the second intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160318027097N7**
Registration date: **2017-12-13, 1396/09/22**
Registration timing: **prospective**

Last update: **2017-12-13, 1396/09/22**
Update count: **0**

Registration date

2017-12-13, 1396/09/22

Registrant information

Name

Ḍr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Gabapentin and Hydroxyzine in pruritus in dialysis patients

Public title

Effect of Gabapentin and Hydroxyzine in pruritus of dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Dialysis patients; pruritus.

Exclusion criteria:

Severe dry skin; Scabies; Psoriasis; Skin lymphoma; Liver cholestasis; Neurological patients; Psychologic patients.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is block, individual and using a random number table in this study. 30 numbers will entered the random block and numbers are randomly assigned into two groups. Accordingly, the patients will receive one of two regimens with their randomly assigned number. In this study, participants, researchers are unaware of prescription drugs.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, participants, researchers are unaware of prescription drugs.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardebil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil , Ardabil , Iran

City

Ardebil

Province

Ardabil

Postal code

5163639888

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

IR.ARUMS.REC.1396.132

Health conditions studied

1

Description of health condition studied

Pruritus

ICD-10 code

L29

ICD-10 code description

Pruritus

Primary outcomes

1

Description

Pruritus

Timepoint

At the beginning of the first intervention, 6 weeks after the first intervention, at the beginning of the second intervention and 6 weeks after the second intervention.

Method of measurement

Pruritus Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet Gabapentin 100mg oral, once in a day for 6 weeks

Category

Treatment - Drugs

2

Description
Intervention group: Tablet Hydroxyzine 25mg oral, once in a day for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Boali hospital
Full name of responsible person
Dr Mohammad Ghorghani
Street address
Boali hospital, Daneshgah Avenue, Ardebil, Iran
City
Ardebil
Province
Ardabil
Postal code
5163639888
Phone
+98 45 3351 2006
Email
naghizadeh73@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr Afshan Sharghi
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
City
Ardabil
Province
Ardabil
Postal code
5163639888
Phone
+98 45 3351 2006
Email
A.sharghi@arums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr Mohammad Ghorghani
Position
دانشجو دستیاری داخلی
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil , Ardabil , Iran
City
Ardabil
Province
Ardabil
Postal code
5163639888
Phone
+98 45 3351 2006
Email
naghizadeh73@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr Sosan Mohammadi Kebar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Ardebil University of Medical Sciences, Daneshgah Avenue, Ardebil, Iran
City
Ardabil
Province
Ardabil
Postal code
5163639888
Phone
+98 45 3351 2006
Email

S.mohammadikebar@arums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Dr Mohammad Ghorghani

Position
Internal Medicine Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Ardabil University of Medical Sciences, Daneshgah Avenue, Ardabil , Ardabil , Iran

City
Ardabil

Province
Ardabil

Postal code
5163639888

Phone
+98 45 3351 2000

Email
naghizadeh73@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Total potential data after unidentifiable individuals

When the data will become available and for how long
Start the access period from 2019

To whom data/document is available
Researchers in academic and scientific institutions

Under which criteria data/document could be used
Data can be used for scientific and research studies.

From where data/document is obtainable
Dr Mohammad Ghorghani; Internal Medicine Assistant; Naghizadeh73@yahoo.com

What processes are involved for a request to access data/document
After receiving the request email, data files will be sent in less than a week.

Comments