Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of pregabalin with doxepin in the management of uremic pruritus

Protocol summary

Summary

Object: Comparison of antipruritic effects of pregabalin with doxepin in the management of uremic pruritus in patients with end stage renal disease undergoing dialysis. Method: 70 patients, aged 16 to 80 years, will be randomly assigned to pregabalin or doxepin. Starting dose of pregabalin is 50 mg three times per week. If response to the medication is not satisfactory, dose of pregabalin will be increased to 50 mg per day. Starting dose of doxepin is 10 mg daily. If response to the medication is not satisfactory, dose of doxepin will be increased to 10 mg two times per day. Patients will be evaluated with 5-D itch scale, visual analogue scale and dermatology life quality index before the intervention and one week, two weeks and four weeks after the intervention. Moreover, adverse effects will be evaluated by checklist of adverse effects at the end of the first and fourth weeks of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060922637N1**
Registration date: **2015-08-29, 1394/06/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-29, 1394/06/07

Registrant information

Name

Naemeh Nikvarz

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5017

Email address

nnikvarz@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregabalin with doxepin in the management of uremic pruritus

Public title

Comparison of pregabalin with doxepin in the management of uremic pruritus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 16-80 years old; undergoing regular hemodialysis or peritoneal dialysis
Exclusion criteria: history of allergy to pregabalin or doxepin; liver failure; pregnancy; history of epilepsy or a single episode of seizure; uncontrolled psychiatric illness; decompensated heart failure; narrow angle glaucoma; hyperthyroidism; history of myocardial infarction in the past three months; heart block; low blood pressure(Systolic blood pressure less than 90 mmHg)

Age

From **16 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Research assistance office of Kerman University of Medical Sciences, Ebne-Sina street

City

Kerman

Postal code

7619813159

Approval date

2015-05-30, 1394/03/09

Ethics committee reference number

IR.KMU.REC.1394.120

Health conditions studied

1

Description of health condition studied

ESRD

ICD-10 code

N 18.5

ICD-10 code description

End stage kidney disease on dialysis

Primary outcomes

1

Description

Severity of pruritus

Timepoint

Before the intervention, and one week, two weeks and four weeks after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Severity of pruritus and its impact on the quality of life

Timepoint

Before the intervention, and one week, two weeks and four weeks after the intervention

Method of measurement

5-D itch scale

2

Description

Effect of pruritus on the quality of life

Timepoint

Before the intervention and one week, two weeks and four weeks after the intervention

Method of measurement

Dermatology Life Quality Index (DLQI)

3

Description

Adverse effects

Timepoint

At the end of the first and fourth weeks of the intervention

Method of measurement

Checklist of adverse effects

Intervention groups

1

Description

Pregabalin (Oral Capsule 50 mg): The initial dose of pregabalin is 50 mg three times a week (after each dialysis session in hemodialysis patients). After one week, if response to the medication is not satisfactory, dose will be increased to 50 mg per day. Duration of the study is 4 weeks.

Category

Treatment - Drugs

2

Description

Doxepin (Oral Capsule 10 mg): The initial dose of doxepin is 10 mg per day. After 1 week, if response to the medication is not satisfactory, dose of the drug will be increased to 10 mg two times per day. Duration of the study is four weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Naemeh Nikvarz
Street address
Kowsar Boulevard
City
Kerman

2

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Naemeh Nikvarz
Street address
Imam Khomeini Highway
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Kerman

3

Recruitment center
Name of recruitment center
Javad-ol Aemeh Dialysis Center
Full name of responsible person
Naemeh Nikvarz
Street address
Alley No 25, North Abouzar Street
City
Kerman

4

Recruitment center
Name of recruitment center
Ali-ebne Abitaleb Hospital
Full name of responsible person
Nazanin Foroutan
Street address
West Mofateh Boulevard, Ali-ebne Abitaleb Square
City
Rafsanjan

5

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Nazanin Foroutan
Street address
Ebne sina Street
City
Sirjan

6

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Nazanin Foroutan
Street address
Pasdaran Alley, Chamran Street
City
Zarand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mrs. Hasani
Street address
Office of research affair of Kerman University of Medical Sciences, Ebne-Sina Street
City
Kerman
Grant name
Grant code / Reference number
94/109
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
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Person responsible for updating data

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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