

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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

City

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

Full name of responsible person

Naemeh Nikvarz

Position

Assistant Professor/PhD

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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