

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of pregabalin in treatment of uremic restless leg syndrome

Protocol summary

Summary

This study is aimed for evaluation of pregabalin effect on symptoms of uremic restless legs syndrome. Inclusion criteria are as followed: End-stage renal disease, Restless legs syndrome Exclusion criteria are as followed: Iron deficiency anemia, hypoglycemia, hypercalcemia, treatment with drugs effective for RLS The study population are a group of ESRD patients, admitted in dialysis ward of Imam Reza Hospital of Kermanshah. Sample size is 78 patients including intervention and control groups. Intervention include a period of 12 weeks treatment with pregabalin 50 mg once daily. Primary outcome is severity of RLS symptoms measured by questionnaire at the beginning and end of study and comparing between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072312685N9**

Registration date: **2017-08-20, 1396/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Hamidreza Omrani

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6302

Email address

hamidomrani@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pregabalin in treatment of uremic restless leg syndrome

Public title

Effect of pregabalin in treatment of uremic restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of ESRD; restless leg syndrome; signing of the informed consent. Exclusion criteria: anemia; iron deficiency; treatment with other restless leg syndrome specific drugs; hypercalcemia; hypocalcemia; sensitivity to pregabalin; patient who reject cooperate for follow up

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Science and Health Services

Street address

Shahid Beheshti ave. Kermanshah

City

Kermanshah

Postal code

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

Kums.rec.1396.185

Health conditions studied

1

Description of health condition studied

Restless leg syndrome

ICD-10 code

G25.8

ICD-10 code description

Other specified extrapyramidal and movement disorders

Primary outcomes

1

Description

Severity of restless legs syndrome symptoms

Timepoint

Beginning and end of study

Method of measurement

International restless legs syndrome study group rating scale(IRLS)questionnaire

Secondary outcomes

1

Description

Drug side effects

Timepoint

The entire study priod

Method of measurement

By patients report

Intervention groups

1

Description

pregabalin treatment with starting dose 50 mg once daily and gradually titrated up to 100 mg once daily it tolerated for a priod of 12 week.

Category

Treatment - Drugs

2

Description

The control group are treated with placebo for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Ward of Imam Reza Hospital

Full name of responsible person

Dr hamidreza Omrani MD Associate Professor, Dialysis ward

Street address

Imam Reza Hospital, Sorkheligeh

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Behruz Hamze Vice-Chancellor of Research and Technology

Street address

Shahid Beheshti Ave. Building n:2 of University

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Internal Medicine Department of Kermanshah Faculty of Medicine

Full name of responsible person

Dr Shilan Haseli

Position

Internal Medicine Resident

Other areas of specialty/work**Street address**

Imam Reza Hospital, Sorkheligeh

City

Kermanshah

Postal code**Phone**

+98 83 3427 6330

Fax**Email**

Shilan.haseli@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Internal Medicine Department of Kermanshah Faculty of Medicine

Full name of responsible person

Dr Hamidreza Omrani

Position

Associate Professor, Department of Internal Medicine

Other areas of specialty/work**Street address**

Imam Reza Hospital, Sorkheligeh

City

Kermanshah

Postal code**Phone**

+98 83 3427 6330

Fax**Email**

Hamidomrani@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Internal Medicine Department of Kermanshah Faculty of Medicine

Full name of responsible person

Dr Hamidreza Omrani

Position

Associate Professor Department of Nephrology

Other areas of specialty/work**Street address**

Imam Reza Hospital, Sorkheligeh

City

Kermanshah

Postal code**Phone**

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Fax**Email****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