# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 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 uremicrestless legs syndrome. Inclusion criteria are as followed: End-stage renal disease, Restless legs syndrome Exclusion criteria are as followed: Iron deficiency anemia, hypoglycemia, hyprcalcemia, treatment with drugs effective for RLS The study population are a group a 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

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**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 cooprate 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**
pregabaline 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**

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## Person responsible for scientific inquiries

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**Position**

Associate Professor, Department of Internal Medicine

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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**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*