

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of therapeutic effects of Gabapentin versus Levodopa-c on Restless legs syndrome in hemodialysis patientes

#### Protocol summary

##### Summary

Restles Legs syndrome is one of the sleep disorders that have variables causes including: Iron deficiency anemia, pregnancy, Uremia, idiopathic, etc. RLS is common in uremic patient. In this study we are going to compare the efficacy of gabapentin versus levodopa-c in hemodialysis patients in hemodialysis center of Kermanshah Emam Reza hospital. Inclusion criteria for patients is fulfilling 4 criteria of IRLSSG (International Restless Legs Syndrom Study group) which indicate moderate to severe RLS. The patients will evaluate for pregnancy and some other causes of RLS As exclusion criteria. The patients will evaluated in three stages. At first for 4 wks they treated by Gabapentin, the second stage is 2 wks washout and the third stage is 4 wks treatment by levodopa -C. For evaluation of effect of each drug we evaluate the patients with IRLSSG scale, SF-36 (scale of evaluation of quality of life), Pittsburg sleep quality index (PSQI) and Epworth sleepiness scale (ESS) before and after drug administration. Hb, TIBC, ferritin and serum iron also will be ckeked for control and comparison.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112078323N1**  
Registration date: **2012-01-15, 1390/10/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-01-15, 1390/10/25

##### Registrant information

Name

Nazanin Razazian

##### Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1427 3409

##### Email address

nrazazian@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Pro\_vice\_chancellor for research of Kermanshah University of Medical Sciences

##### Expected recruitment start date

2011-10-23, 1390/08/01

##### Expected recruitment end date

2012-01-21, 1390/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of therapeutic effects of Gabapentin versus Levodopa-c on Restless legs syndrome in hemodialysis patientes

##### Public title

Comparative study of therapeutic effects of Gabapentin versus Levodopa-c on Restless legs syndrome in hemodialysis patientes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria :minimal time of hemodialysis : 3 mount  
:IRLSSG scale more than 10: Patient`s age more than 15

years Exclusion criteria: Under treatment with psychotropic agents during recent 2 weeks:presence of another neurologic disease comorbid with ESRD for example CVA, MS and etc.:Iron deficiency anemia:Pregnancy

#### Age

From **15 years** old to **100 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size:

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### 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

2011-11-16, 1390/08/25

#### Ethics committee reference number

7/420/پ

## Health conditions studied

### 1

#### Description of health condition studied

RLS: Restless Legs syndrome.

#### ICD-10 code

G 25.8

#### ICD-10 code description

Other specified extrapyramidal and movement disorders

## Primary outcomes

### 1

#### Description

severity of RLS

#### Timepoint

At first & 4 wks after first drug administration before second drug administration & 4 wks after second drug administration (end of the study)

#### Method of measurement

with IRLSSG scale

### 2

#### Description

severity of sleep disorder

#### Timepoint

At first & 4 wks after first drug administration before second drug administration & 4 wks after second drug administration (end of the study)

#### Method of measurement

with pittsburg sleep quality index

### 3

#### Description

quality of life

#### Timepoint

At first & 4 wks after first drug administration before second drug administration & 4 wks after second drug administration (end of the study)

#### Method of measurement

with SF-36 (scale of quality of life)

### 4

#### Description

day time sleepiness

#### Timepoint

At first & 4 wks after first drug administration before second drug administration & 4 wks after second drug administration (end of the study)

#### Method of measurement

Epworth sleepiness scale

## Secondary outcomes

### 1

#### Description

drug advers reaction

#### Timepoint

At first & 4 wks after first drug administration before second drug administration & 4 wks after second drug administration (end of the study)

#### Method of measurement

with question from patients

## Intervention groups

## 1

### Description

capsules of gabapentin 200 mg after evry hemodialysis for 4wks 2hours befor sleep

### Category

Treatment - Drugs

## 2

### Description

tablet levodopa -c 110mg nightly 2 hours befor sleep for 4 wks

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Hemodialysis center of Kermanshah Emam Reza Hospital

#### Full name of responsible person

Dr Nazanin Razazian

#### Street address

Imam Reza Hospital, Sorkheligeh

#### City

Kermanshah

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Sponsor name 1 Vice-chancellor of Research and Technology of Kermanshah University of Medical

#### Full name of responsible person

Dr Farid Najafi the vice-chancellor of research and technology

#### Street address

Building n:2 of university, Shahid Beheshti ave, Kermanshah, Iran

#### City

Kermanshah

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sponsor name 1 Vice-chancellor of Research and Technology of Kermanshah University of Medical

#### 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

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

#### Full name of responsible person

Dr Nazanin Razazian

#### Position

Assistant Professor, Department of Neurology

#### Other areas of specialty/work

#### Street address

Imam Reza hospital, Sorkheligeh

#### City

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#### Postal code

#### Phone

+98 83 1427 6309

#### Fax

#### Email

Nrazazian@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

#### Full name of responsible person

Dr Hamid Azimi

#### Position

Neurology resident

#### Other areas of specialty/work

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Imam Reza hospital, Sorkheligeh

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#### Email

Hamidazimi76@yahoo.com

#### 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*