

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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)

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+98 83 1427 3409

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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

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Person responsible for updating data

Contact

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Full name of responsible person

Dr Hamid Azimi

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Neurology resident

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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