

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparative study of therapeutic effects of Gabapentin versus placebo on Restless legs syndrome in hemodialysis patients

Protocol summary

Summary

1-Objectives: The aim of our study was to find the efficacy of gabapentin in a low dose of 100mg only three times a week among hemodialysis(HD) patients with restless leg syndrome(RLS) . 2-design: All Patients of hemodialysis emam Khomeini hospital center.double blind, placebo control.single center. crossover clinical trial.109 patients.simple randomization.Trial phase not applicable. 3-setting and conduct: patients fulfilled the criteria of RLS were randomized to either gabapentin (100 mg) or placebo after HD session for 4 weeks. After 2 weeks of washout period, the patients were switched from gabapentin to placebo or placebo to gabapentin for another 4 weeks. Severity of RLS symptoms before and after management with medication or placebo was evaluated with standardized questionnaire. 4- Participants including major eligibility criteria: All Patients of hemodialysis emam Khomeini hospital center with severity score more than 8. 5-Intervention: drugs and placebo 6- main outcome measures: severity of RLS ;drug adverse effect

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092319273N1**

Registration date: **2015-08-12, 1394/05/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-12, 1394/05/21

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of therapeutic effects of Gabapentin versus placebo on Restless legs syndrome in hemodialysis patients

Public title

Comparative study of therapeutic effects of Gabapentin versus placebo on Restless legs syndrome in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least 3 months of hemodialysis ;international severity scale more than 8 Exclusion criteria: Pregnancy ;Under treatment with psychotropic agents ;presence of another neurologic disease ;Iron deficiency anemia.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 109

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Simple randomization first patient group 1 and second patient group 2 then third patient group 1 and so....

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Ahwaz, Jundishapur University of Medical Sciences

Street address

I.R.Iran - Awz - Zip Code : 61357-15794

City

Ahwaz

Postal code

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Approval date

2014-10-11, 1393/07/19

Ethics committee reference number

ajums.Rec.1393.230

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 restless leg syndrome

Timepoint

At first and 4 weeks after first drug administration and 4 weeks after second drug administration

Method of measurement

with international scale

Secondary outcomes

1

Description

drug adverse reaction

Timepoint

At first and 4 weeks after first drug administration and 4 weeks after second drug administration

Method of measurement

with question from patients

Intervention groups

1

Description

capsules of gabapentin 100mg after every hemodialysis for 4 weeks axir pharmaceutical co.

Category

Treatment - Drugs

2

Description

capsule placebo after every hemodialysis for 4 weeks. the cartridge similar to real capsule was filled with starch powder

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis center of emam khomeini hospital

Full name of responsible person

Sied sifollah beladi musavi

Street address

Golestan

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research and Technology of

Ahvaz, Jundishapur University of Medical Sciences
Full name of responsible person
sied sifollah beladi musavi
Street address
Hemodialysis center of emam khomeini hospital
City
Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor of Research and Technology of
Ahvaz, Jundishapur 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

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Name of organization / entity
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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