Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the effects of Pramipexole and Gabapentin on the treatment of restless leg syndrome in end-stage chronic renal failure patients undergoing hemodialysis

Protocol summary

Study aim
Evaluate the effects of pramipexole and gabapentin on the treatment of RLS in chronic renal failure patients undergoing hemodialysis

Design
Sixty eligible patients are divided into two groups according to the random number table. Patients in the first group are treated with pramipexole and the second group is treated with gabapentin for 4 weeks.

Settings and conduct
In this clinical trial, all chronic renal failure patients undergoing permanent dialysis in the dialysis ward of two hospitals in Bu Ali Sina and Velayat in Qazvin city who have moderate to severe RLS using IRLSSG diagnostic criteria are included . They were randomly divided into pramipexole and gabapentin groups and treated for 4 weeks.

Participants/Inclusion and exclusion criteria
Patients with end-stage chronic renal failure (at least 6 months), under permanent hemodialysis, and with moderate to severe RLS based on IRSLSS diagnostic criteria

Intervention groups
1 - Treatment with pramipexole 0.18 mg daily for 4 weeks 2- Treatment with gabapentin 100 mg daily for 4 weeks

Main outcome variables
The effect of drug use on the severity of RLS based on IRLSSG diagnostic criteria

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191106045350N1**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **retrospective**

Last update: **2019-11-23, 1398/09/02**
Update count: **0**

Registration date
2019-11-23, 1398/09/02

Registrant information
Name
Sepideh Hajian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3335 3824
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s.hajian@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
2018-09-23, 1397/07/01

Actual recruitment end date
2019-03-20, 1397/12/29

Trial completion date
2019-03-20, 1397/12/29

Scientific title
Comparison of the effects of Pramipexole and Gabapentin on the treatment of restless leg syndrome in end-stage chronic renal failure patients undergoing hemodialysis

Public title

Comparison of the effects of Pramipexole and Gabapentin on the treatment of restless leg syndrome in patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with end-stage chronic renal failure (at least 6 months) under permanent hemodialysis Having restless legs syndrome (RLS) based on International RLS Study Group (IRSLSS) diagnostic criteria Moderate to severe RLS based on IRSLSS diagnostic criteria

Exclusion criteria:

Pregnancy Iron deficiency anemia Concomitant neurodegenerative diseases such as cerebrovascular accident (CVA) and Parkinson's disease Lyme disease Complications such as nausea, vomiting, and abdominal pain due to medication use

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using a random number table, with odd numbers assigned to the pramipexole group and even numbers to the gabapentin group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2017-06-13, 1396/03/23

Ethics committee reference number

IR.QUMS.REC.1396.167

Health conditions studied

1

Description of health condition studied

Restless legs syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Disease severity

Timepoint

Before the study and after 4 weeks of treatment

Method of measurement

Severity scale based on International Restless Legs Syndrome Study Group (IRSLSS) diagnostic criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pramipexole 0.18 mg daily for 4 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Gabapentin 100 mg daily for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Dr. Sepodeh Hajian

Street address

Taa'von Sq., 22 Bahman Blvd., Elahieh Kooy, Minodar

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Web page address
http://hosvelayat.qums.ac.ir/Portal/Home/

2

Recruitment center

Name of recruitment center
Bu Ali Sina Hospital

Full name of responsible person
Dr Sepideh Hajian

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Bu Ali Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Amir Peymani

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apeymani@qums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Sepideh Hajian

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Nephrology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No need

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available