Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of gabapentin and pregabalin on neuropathy caused by Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) in patients

Protocol summary

Study aim
Comparative study of the effect of gabapentin and pregabalin on neuropathy caused by Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) in patients

Design
Clinical trial with control group with parallel groups, phase 2-3 on 40 patients

Settings and conduct
This study is performed in Al-Zahra Hospital in Esfahan. Patients will be treated in two ways and the response rate will be assessed by a questionnaire within 1 year.

Participants/Inclusion and exclusion criteria
Inclusion criteria: CIDP-induced neuropathy based on neurologist diagnosis, age over 18 years, no other underlying disease that causes neuropathy, and satisfaction with participation in this study. Exclusion criteria: hypersensitivity to venlafaxine, gabapentin and pregabalin, and dissatisfaction with continuing the study

Intervention groups
Intervention group 1: Patients in the first group will be treated with 37.5 mg of venlafaxine daily with 100 to 500 mg of gabapentin daily. This treatment will continue for patients for 12 months. All questionnaires will be completed by patients before the intervention and once every three months for a year (12 months after treatment). Intervention group 2: Patients in the second group will be treated with venlafaxine 37.5 mg and pregabalin 50 to 300 mg daily. This treatment will continue for patients for 12 months. All questionnaires will be completed by patients before the intervention and once every three months for a year (12 months after treatment).

Main outcome variables
Intensity of patients' body pain and severity of neuropathic pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200217046523N16**
Registration date: **2021-06-13, 1400/03/23**
Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**
Update count: **0**

Registration date
2021-06-13, 1400/03/23

Registrant information

Name
Aryan Rafiee Zadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3837 1582

Email address
rafieezadeh.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-08, 1400/05/17

Expected recruitment end date
2021-09-08, 1400/06/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of gabapentin and pregabalin on neuropathy caused by Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) in patients

Public title
gabapentin and pregabalin on neuropathy caused by Chronic Inflammatory Demyelinating Polyradiculoneuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
CIDP-induced neuropathy based on neurologist diagnosis Age over 18 years No other underlying disease that causes neuropathy Satisfaction with participation in this study
Exclusion criteria:
Hypersensitivity to venlafaxine, gabapentin and pregabalin Dissatisfaction with continuing the study
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
N/A
Randomization description
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 Esfahan University of Medical Sciences
Street address
Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.MUI.MED.REC.1398.070

Health conditions studied

1

Description of health condition studied
Chronic inflammatory demyelinating polyneuropathy
ICD-10 code
G61
ICD-10 code description
Inflammatory polyneuropathy

Primary outcomes

1

Description
Intensity of patients' body pain
Timepoint
Before the intervention and once every three months for a year
Method of measurement
Visual Analogue Scale

2

Description
Severity of neuropathic pain
Timepoint
Before the intervention and once every three months for a year
Method of measurement
Short form of McGill Pain Questionnaire (SF-MPQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in the first group will be treated with 37.5 mg of venlafaxine daily with 100 to 500 mg of gabapentin daily. This treatment will continue for patients for 12 months. All questionnaires will be completed by patients before the intervention and once every three months for a year (12 months after treatment).
Category
Treatment - Drugs

2

Description

Intervention group 2: Patients in the second group will be treated with 37.5 mg of venlafaxine daily and pregabalin 50 to 300 mg daily. This treatment will continue for patients for 12 months. At the beginning of the intervention, as well as once every three months for a year, all questionnaires for patients will be completed and compared with the other group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Keyvan Basiri

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Esfahan

City

Esfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

h.hemasian@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan

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Postal code

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Email

haghjoo.sh@med.mui.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Keyvan Basiri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Keyvan Basiri

Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after people have requested.

When the data will become available and for how long
Six months after publishing the results.

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable
Website of the Research Committee of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments