Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

City
Isfahan

Province
Isfehan

Postal code
8174673118

Phone
+98 31 3668 0048

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

Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0042

Email
basirikeivan@gmail.com

Person responsible for scientific 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

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

City
Esfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0042

Email
basirikeivan@gmail.com

Person responsible for updating data

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
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Esfahan
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
basirikeivan@gmail.com

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