Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A study of comparison of pregabalin, carbamazepine and venlafaxine efficacy to relief painful diabetic neuropathy

Protocol summary

Summary

The main purpose of this study is to achieve the most logical treatment among the common medications for diabetic neuropathy. In a randomized clinical trial among patients referred to diabetes clinic, 240 patients with painful diabetic neuropathy are selected and randomly divided into 3 groups. All the patients have neuropathic pain for at least a month in accordance with the marked inclusion and exclusion criteria . In these three groups, respectively,pregabaline 150 mg , carbamazepine 400 mg and venlafaxine150 mg is prescribed. Obtaining knowingly consent form from the patient and if the patient does not wish to continue, is knowingly excluded. A questionnaire about drug side effects is given to the patient to record drug side effects. At the beginning of the first day and 30th day, laboratory studies and pain measurement in these patients are measured and compared. At the end therapeutic response and complications rates in the three groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302188323N6**
Registration date: **2013-04-06, 1392/01/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-06, 1392/01/17

Registrant information

Name
Nazanin Razazian
Name of organization / entity
Neurology Department of Kermanshah Faculty of Medicine
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of comparison of pregabalin, carbamazepine and venlafaxine efficacy to relief painful diabetic neuropathy

Public title

Treatment of diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion critreia (Diabetic neuropathy (san antonio critria); Satisfacation ;Not using effective drugs in diabetic neuropathy; No history from seizure; VAS more than 40mm; No history from renal and liver disease , GBS and anemia) Exclusion criteria (Any abnormality in lab test and vital signs; Use antipsychotic drugs or electrical shoch in 30 days ago; Use antidepressant drugs in 14 days ago; Use caspian and lidocain in 7 days ago; Pregnancy and lactation)

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Science
Street address
Shahid Beheshti Street,Kermanshah
City
Kermanshah
Postal code
7313714567
Approval date
2012-11-21, 1391/09/01
Ethics committee reference number
38629

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
G60-G64
ICD-10 code description
Polyneuropathies and other disorders of the peripheral nervous system

Primary outcomes

1

Description
Pain due to diabetic neuropathy
Timepoint
first day , 30th day
Method of measurement
PPI , VAS

Secondary outcomes

1

Description
Changes in sleep and mood
Timepoint
first day , 30th day
Method of measurement
Questionnaire

Intervention groups

1

Description
Tab venlafaxine 75 mg twice a day for 1 month
Category
Treatment - Drugs

2

Description
Cap Pregabaline 150mg daily for 1 month
Category
Treatment - Drugs

3

Description
Tab Carbamazepine 200mg twice a day for a month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabet Clinic of Kermanshah
Full name of responsible person
Baziyar Maryam MD, Rezvan madani Fateme MD
Street address
Taleghani Hospital, Shahid Beheshti Street, Kermanshah ,
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Kermanshah Univesity Of Medical Science

Full name of responsible person

Mohebi Ahmad

Street address

Kermanshah ,Shahid Beheshti Street

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah Univesity Of Medical Science

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

Name of organization / entity

Kermanshah University Of Medical Science

Full name of responsible person

Razazian Nazanin MD

Position

Neurologist

Other areas of specialty/work

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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