

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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, pregabalin 150 mg, carbamazepine 400 mg and venlafaxine 150 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 3409

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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 criteria (Diabetic neuropathy (san antonio criteria); Satisfaction; 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 shock 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 Pregabalin 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
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Person responsible for updating data

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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