

# 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

###### Email address

nrazazian@kums.ac.ir

###### 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  
**Full name of responsible person**  
Razazian Nazanin MD  
**Position**  
Neurologist  
**Other areas of specialty/work**  
**Street address**  
Emam Reza Hospital, Kermanshah  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Kermanshah University Of Medical Sciences  
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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*