

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparative study of combination Gabapentin and topiramate vs treatment alone topiramate or Gabapentin of painful diabetic neuropathy

Protocol summary

Summary

The aim of this study is to compare the effects of combination of gabapentin and topiramate with gabapentin or topiramate monotherapy in the treatment of painful diabetic neuropathy. In this randomized clinical trial, 150 patients with diabetes from the Kermanshah Diabetes Research Center for treatment of painful diabetic neuropathy will be randomly divided into three groups (n=50). In first group, treatment started with 50mg/daily topiramate and patients visited respectively at day 15, 30, 60 and 90 and drug dose increases based on treatment response and patient tolerance if necessary, respectively, 100, 200, and maximize 400 mg. In second group, gabapentin started by 300 mg/daily and like the first groups are examined. The third group combination of 25mg topiramate and 100mg gabapentin will start and on the basis of response to treatment and patient tolerance the dose will increased. At the end of treatment improvement of painful diabetic neuropathy, changes in HbA1c, cholesterol, triglyceride changes and patient weight in the three groups will compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108287432N1**

Registration date: **2012-01-12, 1390/10/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-12, 1390/10/22

Registrant information

Name

Parviz Soufivand

Name of organization / entity

Kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1837 2910

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psoufivand@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2011-11-16, 1390/08/25

Expected recruitment end date

2012-05-14, 1391/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative study of combination Gabapentin and topiramate vs treatment alone topiramate or Gabapentin of painful diabetic neuropathy

Public title

The comparative study of combination Gabapentin and topiramate vs treatment alone topiramate or Gabapentin of painful diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: 1 - diabetes Type II 2 - Dissatisfaction at entering the study, 3 - Failure to receive medication to control pain when the study began, 4 - exposure to neuropathic pain from diabetes. Exclusion criteria: kidney disease - pregnancy -

breastfeeding - a history of liver disease - while taking anti-seizure- taking OCP - a history of sensitivity to Astazvlamydya - other causes for neuropathy, such as MS-CVA

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 sciences

Street address

Shahid beheshti Blvd

City

Kermanshah

Postal code

Approval date

2011-03-12, 1389/12/21

Ethics committee reference number

2000305

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

E10.4

ICD-10 code description

Insulin-dependent diabetes mellitus with neurological complications

Primary outcomes

1

Description

improvement of painful diabetic neuropathy

Timepoint

Day 15, 30, 60 and 90

Method of measurement

Based on TCSS

Secondary outcomes

1

Description

changes in HbA1c

Timepoint

Day 15, 30, 60, 90

Method of measurement

Based on laboratory assessment

2

Description

changes in triglycerid

Timepoint

Day 15, 30, 60, 90

Method of measurement

based on laboratory assessment

3

Description

changes in cholestrol

Timepoint

Day 15, 30, 60, 90

Method of measurement

based on laboratory assessment

Intervention groups

1

Description

In second group, gabapentin started by 300 mg/daily and like the first groups are examined.

Category

Treatment - Drugs

2

Description

In first group, treatment started with 50mg/daily topiramate and patients visited respectively at day 15, 30, 60 and 90 and drug dose increases based on treatment response and patient tolerance if necessary, respectively, 100, 200, and maximize 400 mg.

Category

Treatment - Drugs

3

Description

The third group combination of 25mg topiramate and 100mg gabapentin will start and on the basis of response to treatment and patient tolerance the dose will increased

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Diabetes Research Center

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

No. 2, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

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 Sciences

Full name of responsible person

Dr. MehrAli rahimi

Position

Endocrinologist

Other areas of specialty/work

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City

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Person responsible for scientific inquiries

Contact

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Name of organization / entity

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Other areas of specialty/work

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Web page address

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