Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation Of Topiramate Efficacy On Neuropathic Pain In Patients With Diabetic Polyneuropathy

Protocol summary

Summary

Objective: This study is designed to evaluate the efficacy of Topiramate on pain in diabetic polyneuropathy and compare it with the known drug Gabapentin. Design: This study is a clinical trial in Mostafa Khomeini Hospital performed on patients with painful diabetic polyneuropathy. All cases are simply divided in two group equally. Setting and conduct: One hundred patients selected in intervention group named group one and take Topiramate one hundred milligram daily twelve weeks and patients in group two (control group) take Gabapentin nine hundred milligrams daily for the same period. Pain intensity is evaluated every two weeks in both groups with visual analogue scale (VAS) which is a standard scale for pain intensity. Study design and aims are explained completely for all patients and all patients have a written consent. The coworkers who evaluate the patieints are blinded to drugs. Selected patients are between 35 to 75 years old with at least 8 years history of diabetes. Patients with any history pain to other causes, use of other pain killer drugs or any history of allergy to the above drugs are not permitted in this study. Thirty millimeter decrease in VAS score is a significant response. The main aim of this study is searching drug for helping to relieve pain in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110330680N1**
Registration date: **2017-02-04, 1395/11/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-04, 1395/11/16

Registrant information

Name
Siamak Afshinmajd
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8896 9438
Email address
afshin@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed university. This study is a dissertation in general medicine degree.

Expected recruitment start date

2008-12-31, 1387/10/11

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Of Topiramate Efficacy On Neuropathic Pain In Patients With Diabetic Polyneuropathy

Public title

Topiramate In Diabetic Polyneuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 35t0 75 years old; painful diabetic polyneuropathy; more than 8 year duration of disease; Exclusion criteria: Pain due to other cause; Taking any other pain killer drugs; History of allergy to drugs; Do not meet the criteria of ethical committee of

shahed University;

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients who meet the criteria of study select by researchers assigned every other in intervention and control groups. Coworkers who are blind to group of patients or kind of drug evaluate the patients and finally patients complete the questionnaire.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shahed University

Street address

Shahed University, Infront Of Emam Khomeini Tomb, Khalije Fars High Way

City

Tehran

Postal code

00982166495832-4

Approval date

2007-10-16, 1386/07/24

Ethics committee reference number

Shahed.REC.1386.1

Health conditions studied

1

Description of health condition studied

Diabetic Polyneuropathy

ICD-10 code

G63.2

ICD-10 code description

Diabetic polyneuropathy (E10-E14 with common fourth character .4+)

Primary outcomes

1

Description

Pain In Diabetic Polyneuropathy

Timepoint

In the beginning of study and then every two weeks to three months

Method of measurement

Questionnaire Completed By Researchers And International Standard Scale Of (VAS)

Secondary outcomes

1

Description

Drowsiness

Timepoint

Every two weeks

Method of measurement

Questionnaire Completed By researchers from patient complaints

2

Description

redness or pruritus of skin(hypersensitivity to drugs)

Timepoint

Two weeks after starting the study and then every two weeks for twelve weeks

Method of measurement

Questionnaire completed By researchers and question from patients

Intervention groups

1

Description

Group One(Intervention) All the selected patients are treated with Topiramate one hundred milligrams daily at night . Dose escalation is gradually over three weeks and patients are evaluated by VAS scale each two weeks for three months

Category

Treatment - Drugs

2

Description

Group Two (control),All patients treat by Gabapentin nine hundred milligrams daily divided in three hundred milligram every eight hour. Pain intensity is measured every two weeks for twelve weeks by VAS scale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mostafa Khomeini Hospital
Full name of responsible person
Hospital Manager or Education Secretary
Street address
Italia Street, Keshavarz. Blvd.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahed University
Full name of responsible person
Zahra Kiasalari, Head Of Research Department.
Street address
Research Department, Shahed University, Tehran-Qom Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahed University
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
Associate Professor Of Neurology.Neurophysiology Research Center.Shahed University
Full name of responsible person
Siamak Afshin majd
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Person responsible for updating data

Contact
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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