

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 patients 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)

Phone

+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 35 to 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

Position

Neurologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Research Center, Shahed University

Full name of responsible person

Siamak Afshin majd

Position

Neurologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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