

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A Comparison of Effectiveness of Amitriptyline and Topiramate in the Treatment of Painful Diabetic Neuropathy

Protocol summary

Summary

The purpose of study is comparison of effectiveness of Amitriptyline and Topiramate in the treatment of painful diabetic neuropathy Inclusion criteria :From both genders selected who were between 18-80 years of age and were under anti hyperglycemic agents therapy with diabetic peripheral neuropathy symptoms in the form of pain and paresthesia in rest for at least 1 month. Exclusion criteria : persons with any important clinical disease, unstable clinical or psychologic disease , other neuropathic causes ,renal dysfunction ,liver disease , epilepsy ,psychiatric disease ,uncontrolled HTN ,malignancy ,opiate addiction ,anti epileptic ,anti depressant , topical anti pain or opioid treatment,pregnant and lactating women and need to change treatment. Target sample :patients with diabetic neuropathy Sample size : 60 Single blind study Time : one year Primary outcomes : 1. Effectiveness of Amitriptyline in the treatment of Painful Diabetic neuropathy on VAS suggest 2. Effectiveness of Topiramate in the treatment of painful diabetic neuropathy on VAS suggest 3. Comparison of Effectiveness of Amitriptyline and Topiramate in the treatment of painful diabetic neuropathy 4. Comparison changes of fasting plasma sugar , glycosilated hemoglobulin ,total cholestrol ,triglyceride ,high density lipoprotein , creatinine between two groups Patients divided into two groups ,control and interventional . Control group are teared with Amitriptyline and interventional group are treated with topiramate for up to three months and the results are compared .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210113565N6**

Registration date: **2012-12-29, 1391/10/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-29, 1391/10/09

Registrant information

Name

Akbar Aliasgarzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of Effectiveness of Amitriptyline and Topiramate in the Treatment of Painful Diabetic Neuropathy

Public title

A Comparison of Effectiveness of Amitriptyline and Topiramate in the Treatment of Painful Diabetic Neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :patients with diabetes mellitus ; both genders ; between 18-80 years of age ; under anti hyperglycemic agents therapy ;with diabetic peripheral neuropathy symptoms in the form of pain and paresthesia in rest for at least 1 month. Exclusion criteria : persons with any important clinical disease; unstable clinical or psychologic disease ; other neuropathic causes ;renal dysfunction ;liver disease ; epilepsy ;psychiatric disease ;uncontrolled HTN ;malignancy ;opiate addiction ;anti epileptic ,anti depressant , topical anti pain or opioid tretmant ;pregnant and lactating women ; need to change treatment.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tabriz University of Medical Science

Street address

University st , Janbazan Square

City

Tabriz

Postal code

Approval date

2012-09-09, 1391/06/19

Ethics committee reference number

9192

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

G99.0

ICD-10 code description

Autonomic neuropathy in endocrine and metabolic diseases

Primary outcomes

1

Description

Response to treatment

Timepoint

3 month

Method of measurement

History and Physical Exam , EMG/NCV if needed

Secondary outcomes

empty

Intervention groups

1

Description

Intervention : Tablet Topiramate 50 mg ,twice daily ,duration 3 month

Category

Treatment - Drugs

2

Description

Control : Tablet Amitriptyline 25 mg , twice daily , for 3 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Subspecial and Special Clinics of Tabriz university of Medical Sciences

Full name of responsible person

Seyyed Hasan Fazlazar Sharabiani

Street address

Tabriz University of Medical Sciences, Tabriz , East Azarbayjan ,Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrine Research Centre of Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Akbar Aliasgharzadeh

Street address

Emam Reza Hospital

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrine Research Centre of Tabriz 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

Endocrine Research Centre

Full name of responsible person

Seyyed Hasan Fazlazar Sharabiani

Position

Doctor of Medicine

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Endocrine Research Center

Full name of responsible person

Dr. Akbar Aliasghar Zadeh

Position

Endocrinologist

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Web page address

Person responsible for updating data

Contact

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