

# 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)

###### Phone

+98 41 1335 7850

###### Email address

asgharzadeha@tbzmed.ac.ir

##### 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**

**Street address**

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Endocrine Research Center

**Full name of responsible person**

Dr. Akbar Aliasghar Zadeh

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**Other areas of specialty/work**

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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*