Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 syptoms 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 neurupathic causes ,renal dysfunction ,liver disease , epilepsy ,psychiatric disease ,uncontroled 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 hemoglubolin ,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

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Name of organization / entity
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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 syptoms 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 neurupathic causes ;renal dysfunction ;liver disease ; epilepsy ;psychiatric disease ;uncontroled 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
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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