Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparison of Effect of Dulextine and Nortryptiline in Diabetic Neuropathy

Protocol summary

Summary

Type 2 diabetes is the most common metabolic disease, and its prevalence is increasing, This disease has many complications, among them diabetic neuropathy is considered as one of the most common complications in both type 1 and type 2 diabetes. This study will be done as clinical trial and population are all patients with diabetic neuropathy who have been pre-treated with nortriptyline 25-75 mg (54 patients).The main objective is to compare the effect of duloxetine and nortriptyline for diabetic neuropathy. Inclusion criteria: patients older than 18 years with least 3 years of diabetic record, patients with painful diabetic neuropathy, patients who were pre-treated with nortriptyline 25-75 mg . Exclusion criteria: patients with epilepsy, patients with uncontrolled severe HTN, chronic liver disease or kidney disease, patients with other causes of pain are treated. These patients will not taken drugs for 1 month and again for 3 months on Duloxetine 60 mg. In this study, investigation and interpretation of pain were done on VAS scale (Visual Analogue scale) that is based on pain intensity score. From 3-1 to 6-4 were pointed for mild pain and moderate pain and severe pain score is 9-7. Patients are visited at the end of the third month and are rated based on pain intensity of 9-1and finally total score is summed for each patient and total score of three month is extracted based on the number and based on the severity. Given that the pain intensity in previous period with nortriptyline is compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111113612N7**
Registration date: **2016-05-05, 1395/02/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name
Farzad Najafipour
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7850
Email address
najafipourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-16, 1394/12/26

Expected recruitment end date

2016-07-15, 1395/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of Effect of Dulextine and Nortryptiline in Diabetic Neuropathy

Public title

A Comparison of Effect of Dulextine and Nortryptiline in Diabetic Neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients older than 18 years are at least 3 years have passed since the risk of diabetes, patients with painful diabetic neuropathy, patients who for at least three months before nortriptyline were 25-75 mg. Exclusion criteria: patients with epilepsy, patients with uncontrolled HTN severe, chronic liver disease or kidney disease, patients with other causes of pain are treated.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Postal code

Approval date

2016-03-14, 1394/12/24

Ethics committee reference number

TBZMED.REC.1394.1187

Health conditions studied

1

Description of health condition studied

Diabetes 2

ICD-10 code

G63.2

ICD-10 code description

polyneuropathy

Primary outcomes

1

Description

Pain and burning

Timepoint

Baseline, one month after discontinuation of the Nortriptyline, after 3 months of initiating Deloxetine

Method of measurement

Based on questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In all patients, administration of duloxetine 60 mg daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The doctor Farzad Najafipour's office

Full name of responsible person

Doctor Farzad Najafipour

Street address

The doctor Farzad Najafipour's office, Third floor, spring Building, Golgasht Street, Tabriz, East Azerbaijan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Vice chancellor for Research of Tabriz University of Medical Sciences,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City
Tabriz
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 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Farzad Najafipour
Position
Endocrinology and Metabolism/ Associate Professor
Other areas of specialty/work
Street address
Department of Endocrinology, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Postal code
Phone
+98 41333557850
Fax
Email
Najafipourf@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Farzad Najafipour
Position
Endocrinology and Metabolism/Associate Professor
Other areas of specialty/work
Street address
Department of Endocrinology, Imam Reza Hospital, Tabriz university of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Postal code
Phone
+98 41333557850
Fax
Email
Najafipourf@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz Medical University
Full name of responsible person
Dr. Mohammad Rashidian
Position
MD, Resident of Internal Medicine
Other areas of specialty/work
Street address
Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Postal code
Phone
+98 413782751
Fax
Email
malekanimohamad@gmail.com
Web page address

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