Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Pentoxifylline on diabetic neuropathy in patients with type 2 diabetes

Protocol summary

Summary

This study aimed to determine the Effect of Pentoxifylline of diabetic neuropathy of patients with type 2 diabetic deals.This study is a double blind clinical trial.Type 2 diabetic patients between the ages of 40 to 75 years over an year,are the inclusion criteria for this study,and people with heart,kidney and liver disease,and or with a history of amputation,pregnancy and lactation have been excluded.According to inclusion and exclusion criteria of the study and after confirmation of patient's neuropathy,70 people are divided into two groups of 35 persons to intervention and placebo by block random way.To one group;Pentoxifylline and to another one placebo and vitamin B is given.Before and after intervention,symptoms of distal polyneuropathy will be recorded by A Michigan questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051827965N1**
Registration date: **2016-09-23, 1395/07/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-23, 1395/07/02

Registrant information

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Recruitment status

Recruitment complete

Funding source

Deputy for Research,Qom University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pentoxifylline on diabetic neuropathy in patients with type 2 diabetes

Public title

Effect of Pentoxifylline on diabetic neuropathy in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:type 2 diabetes over a year;age group40-75;Distal polyneuropathy resolutions based on questionnaires Michigan;HBA1C8% -10% Exclusion criteria:Kidney,liver,and heart failure based on the tests, history and physical exam;High blood pressure more than 160 mm Hg and advanced diabetic Retinopathy;The recent use of drugs for neuropathy {gabapentin , nortriptyline};Fever;Pergnancy and lactation;History of amputation

Age

No age limit

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
70

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qom University of Medical Sciences
Street address
Plaque 83,4th Alley,1st Lane,Safashar Street.
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3716987366
Approval date
2016-05-01, 1395/02/12
Ethics committee reference number
IR.MUQ.REC.1395.12

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
FBS
Timepoint
pre and early post-operation
Method of measurement
Based on Labratory

2

Description
HBA1C
Timepoint
pre and early post-operation
Method of measurement
Based on Labratory

Secondary outcomes

1

Description
Distal polyneuropathy
Timepoint
Before and 4 months after the intervention
Method of measurement
Michigan Questionnaire A

Intervention groups

1

Description
The tablet of pentoxifylline 400 mg and 100 mg tablets B1 , twice a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaid Beheshti Hospital
Full name of responsible person
Dr.Parham
Street address
Qom,Shahid Beheshti st.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy for Research,Qom University of Medical Sciences
Full name of responsible person
Dr.Saghafi
Street address
Safashar
City
Qom

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy for Research,Qom 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

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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