

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

###### Name

Farhad Hosseini

###### Name of organization / entity

Qom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

fhoseini@muq.ac.ir

###### 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 group 40-75; Distal polyneuropathy resolutions based on questionnaires Michigan; HbA1C 8% -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; Pregnancy 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.

##### City

Qom

##### Postal code

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 Laboratory

### 2

#### Description

HBA1C

#### Timepoint

pre and early post-operation

#### Method of measurement

Based on Laboratory

## 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.

##### City

Qom

## 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

### Contact

**Name of organization / entity**  
Medical University  
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Dr.Hosseini  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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