

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Efficacy of nortriptyline and duloxetine for diabetic neuropathy type 2

Protocol summary

Summary

The study was double-blind clinical trial population test all patients with painful diabetic neuropathy are caused by hospital clinic of Ayatollah Rohani visit and sample selection by statistical consultant Mr. plan, as random and using computer matching list case number and the type of treatment desired (known as A and B for each treatment group) were determined and the researcher placed, inclusion criteria: patients over 18 years of age and At least three years have passed since the risk of diabetes and with pdn (painful diabetic neuropathy) For at least a month are. Exclusion criteria: patients with epilepsy, htn uncontrolled and chronic liver disease or renal failure and patients treated for other causes pain in another part of their body. Patients will be divided into two groups (An equal number 40), and Both groups will be 5 weeks under medical treatment. so that a randomly treated with Nortriptyline 25 mg and Duloxetine placebo and another group will be treated with Duloxetine 20 mg and Nortriptyline placebo, methods and interpretation of changes in pain according to VAS (visual analogue scale) will be, all patients taking the drug every week during the phone call will follow

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512265692N8**

Registration date: **2016-02-24, 1394/12/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

Name

Mohammad ali Bayani

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research- Babol University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of nortriptyline and duloxetine for diabetic neuropathy type 2

Public title

Efficacy of nortriptyline and duloxetine for diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients over 18 years of age and At least three years have passed since the risk of diabetes and with pdn (painful diabetic neuropathy) For at least a month are. exclusion criteria: patients with epilepsy, htn uncontrolled and chronic liver disease or renal failure and patients treated for other causes pain in another part of their body.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

As random and using computer matching list case number and the type of treatment desired (known as A and B for each treatment group) were determined and the researcher placed

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Ganj afrooz Street- University of Medical Sciences, Department of Research and Technology

City

Babol

Postal code

47176-41367

Approval date

2015-12-06, 1394/09/15

Ethics committee reference number

MUBABOL.REC.1394.208

Health conditions studied**1****Description of health condition studied**

Diabet

ICD-10 code

E10,E11,E1

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Neuropathic pain

Timepoint

Before the intervention, the duration of the intervention for 35 days, at the end of intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Possible side effects of each drug

Timepoint

During the study period and at the end of the study

Method of measurement

According to Patients

Intervention groups**1****Description**

Intervention Group: nortriptyline, 25 mg tablets(Pharmaceutical Amin),Daily for 35 nights with a number Doluxetine placebo for 35 nights

Category

Treatment - Drugs

2**Description**

control Group: Doluxetine, capsules 20 mg(Pharmaceutical Amin),Daily for 35 nights with a number nortriptyline placebo one night for 35 nights

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Rohani Hospital-Endocrinology clinic

Full name of responsible person

MohammadAli Bayani(Professor of Endocrinology and Metabolism, Dr.)

Street address

Babol-Ganj afrooz Street-Ayatollah rohani Hospital

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research- Babol University of Medical Sciences

Full name of responsible person

Hadi Parsian(Research Assistant)

Street address

Babol-Ganj Afrooz Street-University of Medical Sciences-Vice Chancellor for research

City

Babol

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- Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Mohammad Ali Bayani

Position

Professor of Endocrinology and Metabolism, Dr. (faculty)

Other areas of specialty/work**Street address**

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Person responsible for scientific

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Person responsible for updating data

Contact**Name of organization / entity****Full name of responsible person**

Farshad Fadaee Juybari

Position

Medical Student

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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