Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 11 1223 4651

Email address
m.bayani@mubabol.ac.ir

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

Babol-Ganj Afrooz Street-University of Medical Sciences

City

Babol

Postal code

4717641367

Phone

+98 11 3223 8284

Fax

Email

internalmedbabol@gmail.comfadaeefarshad@gmail.comm.bayani@mubabol.ac.ir

Web page address

mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

MohammadAli Bayani

Position

Endocrinology and Metabolism

Other areas of specialty/work

Street address

Babol-Ganj Afrooz Street-University of Medical Sciences

City

Babol

Postal code

Phone

+98 11 3223 8284

Fax

Email

m.bayani@mubabol.ac.irfadaeefarshad@gmail.comBayanima49@yahoo.com

Web page address

mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Farshad Fadaee Juybari

Position

Medical Student

Other areas of specialty/work

Street address

City

Babol

Postal code

Phone

00

Fax

Email

fadaeefarshad@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