Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effect of nortriptyline and melatonin on the severity of diabetic polyneuropathy

Protocol summary

Study aim
Comparison of the effect of nortriptyline and melatonin on the severity of diabetic polyneuropathy
Design
A randomized, parallel, double-blind, placebo-controlled clinical trial
Settings and conduct
This study will be done on patients referred to endocrinology clinic of Ayatolah Rouhani`s hospital. One group of patients will be given 25 mg of nortriptyline and the other group will be given 3 mg of melatonin. Patients' pain will be assessed at the beginning of the study, at the end of the second week, and at the end of the study based on the VAS (Visual Analogue Scale) scale.
Participants/Inclusion and exclusion criteria
Inclusion criteria: all patients with diabetic neuropathy aged 30-65 years. Exclusion criteria: pregnancy, metabolic and bone diseases, and drug allergy.
Intervention groups
One group received nortriptyline and one group received melatonin
Main outcome variables
Neuropathic pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191030045277N2**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **retrospective**

Last update: **2020-10-15, 1399/07/24**
Update count: **0**
Registration date
2020-10-15, 1399/07/24

Registrant information
Name
mohammadali bayani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-22, 1398/10/01
Expected recruitment end date
2020-09-21, 1399/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of nortriptyline and melatonin on the severity of diabetic polyneuropathy

Public title
The effect of nortriptyline and melatonin on diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with diabetic neuropathy
Exclusion criteria:
Pregnancy and lactation Recent Myocardial Infarction Sensitivity to medications (nortriptyline and melatonin) History of seizures Mood disorder Gastroparesis and

diabetic cystopathy, Liver and Renal failure hypothyroidism and hyperthyroidism people with arthritis Hereditary neuropathies People with a history of trauma and degenerative bone lesions

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random block method with block size 4 (AABB) and the number of blocks 15, patients will be randomly divided into two groups. According to www.randomization.com, Block of 4 will be produced 15 times. To group patients, it will be written on a sheet and assigned to patients. Each patient will be randomly assigned to one of the treatment groups (nortriptyline and melatonin) while receiving the drug, according to the sequence obtained.

Blinding (investigator's opinion)

Double blinded

Blinding description

Melatonin and nortriptyline will be prepared in identical opaque capsules and will be placed in exactly the same cans and packages, and the coding will be done according to a random table. None of the participants, principal investigator, health care personnel (physicians, nurses, etc.) will be responsible for patient care (etc.), data collectors and statistical analysts, will not be aware of patient received package and the coding.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafruze road, Babol town

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.288

Health conditions studied

1

Description of health condition studied

Diabetic polyneuropathy

ICD-10 code

E10.42

ICD-10 code description

Type 1 diabetes mellitus with diabetic polyneuropathy

2

Description of health condition studied

Diabetic polyneuropathy

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description

Severity of neuropathy

Timepoint

At the beginning of the study (first day) and at the end of the second week and at the end of the study (end of the fifth week).

Method of measurement

Based on the VAS (Visual Analogue Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : Patients in this group will be treated with nortriptyline 25 mg (Sobhan Pharmaceutical Company). Its duration will be 35 days.

Category

Treatment - Drugs

2

Description
Intervention group: Patients in this group will be treated with 3 mg melatonin (Razak Pharmaceutical Company) daily.Its duration will be 35 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rohani Hospital
Full name of responsible person
Mohammadali Bayani
Street address
Ganj Afrooz Road, Babol Rohani Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mohammadali Bayani
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mohammadali Bayani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinologist and Metabolism Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
A portion of the data related to the main topic is displayed.

When the data will become available and for how long
Start of access period 6 months after printing result.

To whom data/document is available
It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
No special conditions

From where data/document is obtainable
Babol University of Medical Sciences, Internal Education, Dr. Mohammad Ali Bayani

What processes are involved for a request to access data/document
Refer to internal training and talk to Dr. Bayani and access to information

Comments