

# 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 Ayatollah 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3223 8284

##### Email address

bayanima49@yahoo.com

#### 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](http://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

Babol

##### Province

Mazandaran

##### Postal code

47176-47745

##### Phone

+98 11 3223 8309

##### Email

info@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Mohammadali Bayani

##### Street address

Ganj Afrooz Road, Babol Rohani Hospital

##### City

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##### Province

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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

#### Street address

Ganj Afrooz Road, Babol Rohani Hospital

#### City

Babol

#### Province

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bayanima49@yahoo.com

## Person responsible for scientific inquiries

### Contact

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Babol University of Medical Sciences

#### Full name of responsible person

Mohammadali Bayani

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

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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**