

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of pregabalin and melatonin on the Severity of Pain caused by painful diabetic polyneuropathy, a double-blind clinical trial study

Protocol summary

Study aim

Comparison of the effect of pregabalin 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 75 mg of pregabalin 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 pregabalin and one group received melatonin

Main outcome variables

Neuropathic pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045277N3**

Registration date: **2024-02-09, 1402/11/20**

Registration timing: **prospective**

Last update: **2024-02-09, 1402/11/20**

Update count: **0**

Registration date

2024-02-09, 1402/11/20

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

2024-04-03, 1403/01/15

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of pregabalin and melatonin on the Severity of Pain caused by painful diabetic polyneuropathy, a double-blind clinical trial study

Public title

he effect of pregabalin 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
History of seizures Gastroparesis and diabetic cystopathy
Sensitivity to medications (pregabalin and melatonin)
Mood disorder hypothyroidism and hyperthyroidism Liver
and Renal failure 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

No information

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 (pregabalin and melatonin) while receiving the drug, according to the sequence obtained.

Blinding (investigator's opinion)

Double blinded

Blinding description

Melatonin and pregabalin 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

2023-08-07, 1402/05/16

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.064

Health conditions studied

1

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 pregabalin 75 mg (Razak 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.roup:

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Mehdi Rajab nia

Street address

Ganj Afrooz Road, Babol Rohani Hospital

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

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 scientific inquiries

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Person responsible for updating data

Contact

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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