

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of melatonin supplement versus placebo on the severity of pain, sleep disorder, and quality of life in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of melatonin supplement versus placebo on the severity of pain. Sleep disorder, and quality of life in patients with painful diabetic neuropathy

Design

This is a double-blind randomized clinical trial, phase II, in which 116 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with painful diabetic neuropathy who will refer to the Imam Khomeini Clinic in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years, Type 2 diabetes for at least one year, Painful neuropathy Exclusion criteria: Pregnancy or breastfeeding, Foot ulcer of infection, Hemoglobin A1c ≤ 9 , Cerebrovascular Diseases and discopathy, Using anti-inflammatory and analgesic drugs, Drinking alcohol or using opioid substances

Intervention groups

Intervention group: Tablet pregabalin 75 mg daily plus tablet melatonin 6 mg twice daily for 8 weeks Control group: Tablet pregabalin 75 mg daily plus tablet placebo twice daily for 8 weeks

Main outcome variables

Primary outcome: Mean score of pain Mean score of sleep disorder Mean score of Clinical Global Impression of Change (CGIC) Secondary outcome: Mean score of quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N299**

Registration date: **2019-09-23, 1398/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-23, 1398/07/01**

Update count: **0**

Registration date

2019-09-23, 1398/07/01

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin supplement versus placebo on the severity of pain, sleep disorder, and quality of life in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Public title

Effect of melatonin supplement versus placebo on the severity of pain, sleep disorder, and quality of life in patients with painful diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 70 years, Type 2 diabetes for at least one year, Painful neuropathy

Exclusion criteria:

Pregnancy or breastfeeding, Foot ulcer of infection, Hemoglobin A1c ≤ 9 , Cerebrovascular Diseases and discopathy, Using anti-inflammatory and analgesic drugs, Drinking alcohol or using opioid substances

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.UMSHA.REC.1398.340

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

Painful diabetic neuropathy

ICD-10 code

E11.40

ICD-10 code description

Type 2 diabetes mellitus with diabetic neuropathy, unspecified

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

Mean score of pain

Timepoint

Before the intervention and at the second, forth, and eighth weeks after the intervention

Method of measurement

Using Visual Analog Scale (VAS)

2**Description**

Mean score of sleep disorder

Timepoint

Before the intervention and at the second, forth, and eighth weeks after the intervention

Method of measurement

Using standard questionnaire

3

Description

Mean score of Clinical Global Impression of Change (CGIC)

Timepoint

Before the intervention and at the eighth week after the intervention

Method of measurement

Using the standard questionnaire

Secondary outcomes

1

Description

Mean score of quality of life

Timepoint

Before the intervention and at the eighth week after the intervention

Method of measurement

Using the SF-36 questionnaire

Intervention groups

1

Description

Intervention group: Tablet pregabalin 75 mg daily plus tablet melatonin 6 mg twice daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Tablet pregabalin 75 mg daily plus tablet placebo twice daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

mam Khomeini Clinic in Hamadan City

Full name of responsible person

Maryam Shokri

Street address

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

maryamshokri993@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Shokri

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

maryamshokri993@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Maryam Mehrpooya

Position

Clinical Pharmacists

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Fax**Email**

m_mehrpooya2003@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available