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

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
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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
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
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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