Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effect of coenzyme Q10 versus placebo as an adjuvant therapy on pain in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of coenzyme Q10 versus placebo as an adjuvant therapy on pain in patients with painful diabetic neuropathy

Design
This is a double-blind randomized clinical trial, phase III, 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 referring 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 examining 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 diabetic neuropathy, Exclusion criteria: Pregnancy or breastfeeding, Foot ulcer or infection, Hemoglobin A1C equal to or less than 9, Cerebrovascular diseases or discopathy, Taking anti-inflammatory medications, Using alcohol or opioids

Intervention groups
Intervention group: Pregabalin tablet 75 mg (manufactured by Golden Life Pharmaceutical Co.) every 12 hours for 8 weeks plus coenzyme tablet Q10 100 mg (manufactured by Reyhaneh Pharmaceutical Co.) every 8 hours for 8 weeks Control group: Pregabalin tablet 75 mg (manufactured by Golden Life Pharmaceutical Co.) every 12 hours for 8 weeks plus placebo tablet including starch (manufactured by laboratory of School of Pharmacy, Hamadan) every 8 hours for 8 weeks

Main outcome variables
Primary outcome: Mean score of painو ean score of sleep disorder

General information

Reason for update
Change in dose of under study medication

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N385**
Registration date: **2021-02-21, 1399/12/03**
Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**
Update count: **1**

Registration date
2021-02-21, 1399/12/03

Registrant information

Name
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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
2021-05-05, 1400/02/15

Expected recruitment end date
2022-02-04, 1400/11/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of coenzyme Q10 versus placebo as an adjuvant therapy on pain in patients with painful diabetic neuropathy: a double-blind randomized clinical trial

Public title

Effect of coenzyme Q10 versus placebo as an adjuvant therapy on pain 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 diabetic neuropathy,

Exclusion criteria:

Pregnancy or breastfeeding, Foot ulcer or infection, Hemoglobin A1C equal to or less than 9, Cerebrovascular diseases or discopathy, Taking anti-inflammatory medications, Using alcohol or opioids

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- 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

2020-11-07, 1399/08/17

Ethics committee reference number

IR.UMSHA.REC.1399.678

Health conditions studied

1

Description of health condition studied

Painful diabetic neuropathy

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Mean score of pain

Timepoint

Before the intervention and at weeks 2 and 4 and 8 after the intervention

Method of measurement

using Visual Analog Scale (VAS)

2

Description

Mean score of sleep disorder

Timepoint

Before the intervention and at weeks 2 and 4 and 8 after the intervention

Method of measurement

Using the Patient Global Impression of Change (PGIC) and Clinical Global Impression of Change (CGIC) questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pregabalin tablet 75 mg (manufactured by Golden Life Pharmaceutical Co.) every 12 hours for 8 weeks plus coenzyme tablet Q10 100 mg (manufactured by Reyhaneh Pharmaceutical Co.) every 8 hours for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Pregabalin tablet 75 mg (manufactured by Golden Life Pharmaceutical Co.) every 8 hours for 8 weeks plus placebo tablet including starch (manufactured by laboratory of School of Pharmacy, Hamadan) every 12 hours for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Clinic in Hamadan city
Full name of responsible person
Paryan Amini
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan University of Medical Sciences
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Paryan Amini
Position
Student of Pharmacy
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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