

# 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 pain's mean 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

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

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

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3832 1371

##### Email

paryan.amini@yahoo.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

Paryan Amini

##### 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

paryan.amini@yahoo.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 Pharmacologist

**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**

m\_mehrpooya2003@yahoo.com

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

**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**