Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of vitamin D consumption on the severity of neuropathic pain in diabetic patients

Protocol summary

Study aim

Studying the effect of vitamin D intake on the severity of diabetic neuropathic pain Determining the relationship between vitamin D levels and the severity of neuropathic pain in patients with vitamin D deficiency and diabetic neuropathy after using vitamin D supplementation Confirmation of diabetic neuropathy by EMG-NCV

Design

Clinical trial in the intervention group before and after treatment, double-blind, phase 2 on 38 patients.

Settings and conduct

Type 2 diabetic patients who referred to Dezful University of Medical Sciences with complaints of diabetic neuropathy symptoms were selected. After Michigan screening, vitamin D levels were measured. Neuropathy in those with vitamin D levels less than 30 was confirmed by nerve and muscle electromyography. Patients received vitamin D supplementation based on vitamin D levels. After treatment, vitamin D levels were measured and Michigan screening was performed. The procedures were performed with the patients' informed consent and during the study, the patients and the evaluator were unaware of the purpose of the study.

Participants/Inclusion and exclusion criteria

Type 2 diabetes Presence of diabetic neuropathy Vitamin D level less than 30 No history of spondylopathy or severe arteriovenous vascular disease No diseases affecting vitamin D metabolism (liver disease, kidney failure)

Intervention groups

First, the patients' history, vitamin D level measurement, and Michigan screening were performed. Then, muscle electromyography was performed to confirm diabetic neuropathy. Based on the vitamin D level, the patients were treated with 50,000 IU vitamin D tablets once a week for a treatment period of 4 to 12 weeks. After treatment, vitamin D level measurement and Michigan screening were performed.

Main outcome variables

Improving the severity of diabetic neuropathy pain in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251102067854N1**
Registration date: **2025-11-23, 1404/09/02**
Registration timing: **retrospective**

Last update: **2025-11-23, 1404/09/02**
Update count: **0**

Registration date

2025-11-23, 1404/09/02

Registrant information

Name

Malihe Moeinjozan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4222 2307

Email address

malihemoeinjozan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

2024-12-21, 1403/10/01

Actual recruitment end date

2025-05-22, 1404/03/01

Trial completion date
2025-05-22, 1404/03/01

Scientific title
Investigating the effect of vitamin D consumption on the severity of neuropathic pain in diabetic patients

Public title
The effect of vitamin D consumption on the severity of diabetic neuropathy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of type 2 diabetes• Possession of a medical record at the Dezful Diabetes Research Center Willingness to participate in the study Presence of diabetic neuropathy People with low vitamin D levels (less than 30).

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **38**
Actual sample size reached: **38**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Dezful University of Medical Sciences

Street address
Dezful Ganjovian Hospital

City
Dezful

Province
Khouzestan

Postal code
6461669969

Approval date
2024-10-16, 1403/07/25

Ethics committee reference number
IR.DUMS.REC.1403.057

Health conditions studied

1

Description of health condition studied
The severity of diabetic neuropathy pain

ICD-10 code
E11.40

ICD-10 code description
Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Michigan Screening Neuropathic Pain Severity Score

Timepoint
Michigan Screening before and after vitamin D supplementation

Method of measurement
Physical examination and Michigan questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 50,000 IU vitamin D tablets, once a week, 4 to 12 weeks based on patients' vitamin D levels

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dezful Ganjovian Hospital

Full name of responsible person
Malihe Moein-Jozan

Street address
Dezful Ganjovian Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dezfoul University of Medical Sciences

Full name of responsible person

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MA.Behmanesh@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice President for Research, Dezful 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

Dezfoul University of Medical Sciences

Full name of responsible person

Malihe Moein-Jozan

Position

Internal medicine specialist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable