

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A study of vitamin D efficacy on prepheral neuropathy in diabetic patients

Protocol summary

Summary

The main purpose of this study is comparison of severity of diabetic neuropathy before and after vitamin D prescription and the possibility of vitamin D usage in treatment of diabetic neuropathy. In a clinical randomized trial; not blinded; without control among patients referred to diabetes clinic of Kermanshah university of medical sciences, 90 patients with painful diabetic neuropathy are selected randomly. All the patients have neuropathic pain for at least a month in accordance with the marked inclusion and exclusion criteria They have vitamin D deficiency (<30ng/ml), no drug history of vitamin D in one year ago, no history of calcium or omega-3 supplements or other effective drugs in vitamin D metabolism or use of other drugs to relief painful neuropathy in 3 last months, no history of diseases can change vitamin D metabolism. There are no other etiologies of neuropathy. They are treated with tab vitamin D 50000 IU once a week for 3 months. The severity of diabetic neuropathy is evaluated before and after the intervention (based on Toronto clinical score system).Then the results are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082014416N1**

Registration date: **2013-08-30, 1392/06/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-30, 1392/06/08

Registrant information

Name

Bahareh Fereidouni

Name of organization / entity

Kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of vitamin D efficacy on prepheral neuropathy in diabetic patients

Public title

A study of vitamin D efficacy on neuropathy in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with diabetes mellitus; both genders; under anti hyperglycemic agents therapy; with diabetic peripheral neuropathy syptoms in the form of pain and paresthesia in rest for at least 1 month and have vitimin D deficiency (<30 ng/ml) and no drug history of vitimin D in one year ago. Neuropathy score in diabetic patients is based on TCSS criteria(6-19 scores) Exclusion criteria: no consent or ability to participate in the study; drug history of calcium or omega;

supplements in 3 last months; drug history of effective drugs in vitamin D metabolism (estrogen, calcitonin...); history of diseases can change vitamin D metabolism (renal and liver diseases, cancers or other endocrine disorders); other etiologies of neuropathy (renal impairment or Cr>2g/dl or GBS) or in examination have radiculopathy; use of other drugs to relief painful neuropathy such as TCA antidepressants, Gabapentin, pregabalin in 3 last months.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

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**

Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Street, Kermanshah

City

Kermanshah

Postal code**Approval date**

2012-11-21, 1391/09/01

Ethics committee reference number

33683

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

Diabetic neuropathy

ICD-10 code

G 63.2*

ICD-10 code description

Diabetic Polyneuropathy

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

Severity of diabetic neuropathy

Timepoint

First day, 3 months later (90th day)

Method of measurement

Toronto Clinical Score System (TCSS)

Secondary outcomes

empty

Intervention groups**1****Description**

Tab Vitamin D 50000 IU once a week for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabet Clinic of Kermanshah University of Medical Science

Full name of responsible person

Mehr Ali Rahimi MD, Bahareh fereidouni MD

Street address

Taleghani Hospital, Shahid Beheshti Street, Kermanshah

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University Of Medical Science, Research vice-presidency

Full name of responsible person

Dr. Farid Najafi

Street address

Kermanshah, Shahid Beheshti Street

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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

Kermanshah Univesity Of Medical Science,Research vice-presidency

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Kermanshah university of medical sciences

Full name of responsible person

Bahareh Fereidouni MD

Position

Internist

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty