Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 siences

Country

Iran (Islamic Republic of)

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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 vitimin D metabolism (estrogen, calcitonin...); history of diseases can change vitimin 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, pergabalin 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 Univesity 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
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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