Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effectiveness of 50000 units of vitamin D orally/weekly for 12 weeks and control group on diabetic neuropathy- before and after study

Protocol summary

Study aim
Effect of Vitamin D on Norpathetic Disease in Patients with Type 2 Diabetes

Design
This was an experimental trial single (before-after) to compare the effectiveness of 50000 units of vitamin D orally/weekly for 12 on diabetic neuropathy. 60 patients (ages 40 to 65 years old), With diagnosis of diabetic neuropathy (through physical examination and earning more than 4 points from Michigan script and not taking supplemental medications and vitamin D in the last 6 months, lack of kidney and liver failure, arthritic inflammatory diseases, rheumatoid arthritis, hyperthyroidism , Malnutrition, and not pregnant are selected and randomly divided into two groups of study and control. The study group receives 50,000 units of vitamin D in 12 weeks orally. In the control group, patients receive a placebo.the severity of neuropathy, Vitamin D and HbA1C will be assessed at baseline and 3 months after the initiation of trial.

Settings and conduct
before-after

Participants/Inclusion and exclusion criteria
ages 40 to 65 years old, diagnosis of diabetic neuropathy

Intervention groups
The study group receives 50,000 units of vitamin D in 12 weeks orally

Main outcome variables
severity of neuropathy; vitamin D; HbA1C

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017102325266N2**
Registration date: **2017-11-08, 1396/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-27, 1397/05/05**
Update count: **1**

Registration date
2017-11-08, 1396/08/17

Registrant information

Name
Akram Ghadiri Anari

Name of organization / entity
Diabetes Research Center

Country
Iran (Islamic Republic of)

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ghadiriam@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, YazdUniversity of Medical Sciences

Expected recruitment start date
2017-11-06, 1396/08/15

Expected recruitment end date
2018-05-05, 1397/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of 50000 units of vitamin D orally/weekly for 12 weeks and control group on diabetic

neuropathy- before and after study

Public title
The effectiveness of vitamin D on diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes, having a medical record at the Yazd diabetes research center, willingness to participate in the study, diagnosis of diabetic neuropathy through physical examination and obtaining a score of more than 4 from the Michigan Neuropathy Screening Questionnaire Instrument (MNSI) aged 40-60 years old,
Exclusion criteria:
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Ethics committee of Yazd University of Medical Science
Street address
Talar honar alley, Bahonar square, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2017-06-20, 1396/03/30
Ethics committee reference number
IR.SSU.REC.1396.71

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
The severity of diabetic neuropathy
Timepoint
Before the intervention, After the intervention
Method of measurement
Michigan Neuropathy Screening Instrument (MNSI)

2

Description
Vitamin D
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

Secondary outcomes

1

Description
HbA1C
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

Intervention groups

1

Description
Subjects receive 50,000 units of vitamin D per week per week for 12 weeks during the intervention period.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabete Research Center
Full name of responsible person
Saeed Hosein Khaklil Zade

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Talar Honar alley, Bahonar square, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
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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
Yazd 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
Yazd University of Medical Science
Full name of responsible person
Marzieh Abutorabi
Position
Assistant Professor, Neurologist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Researcher, MA
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Master
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Psychology

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sepehri_f66@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable participant

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Confidential raw data for secondary analysis will be available to researchers.

From where data/document is obtainable

Ghadiri-Anari Akram 09133534621

What processes are involved for a request to access data/document

Submit a proposal from prestigious academic institution

Comments