

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 Neuropathic 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)

Phone

+98 35 3728 0226

Email address

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

Street address

Talar Honar alley, Bahonar square, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0215

Fax

+98 35 3728 0216

Email

ghadiriam@yahoo.com

Position

Assistant Professor, Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

Street address

Iran, Yazd, Shahid Sadoughi Hospital

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0226

Fax**Email**

marzie.ab@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Shahid Sadoughi Blvd., Bahonar Ave

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3726 3733

Email

mirzaeim@mailfa.com

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

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

Yazd University of Medical Science

Full name of responsible person

Akram Ghadiri-Anari

Position

Associate Professor Endocrinologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Talar honar alley, Bahonar square, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0226

Fax**Email**

ghadiriam@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Science

Full name of responsible person

Fariba Sepehri

Position

Researcher, MA

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Shahid Sadoughi Blvd., Bahonar Ave

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0226

Fax

Email

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