

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of the high dose and conventional regimen of vitamin D effect on antioxidant markers of patients with diabetic foot ulcer

Protocol summary

Study aim

To determine and compare the effectiveness of vitamin D3 treatment regimen with a standard dose and a high dose on antioxidant markers in patients with diabetic foot ulcers.

Design

This is a phase 3 randomized, unblinded clinical trial on 50 patients, who will be randomly divided into 2 groups using block randomization.

Settings and conduct

Patients with diabetic foot ulcers at Imam Khomeini Hospital in Urmia will be assessed based on the severity of their wounds (Wagner classification). Weight and height, time of wound onset, number of wounds, previous hospitalization history for diabetic foot ulcers, and tobacco and alcohol consumption will be recorded. Tests for WBC, PLT, MPV, ESR, CRP, FBS, and HbA1c baseline, vitamin D levels, and MDA, NO, TAC levels will be requested. Within 72 hours of hospitalization, one group will receive weekly treatment with 50,000 units of vitamin D pearls for three weeks, while the second group will receive a single intramuscular injection of 300,000 units of vitamin D. Three weeks after the intervention, the aforementioned tests will be checked routinely for the patients.

Participants/Inclusion and exclusion criteria

Entry criteria: plasma calcium level less than 10 vitamin D level in between 20-30 ng/ml age more than 18 years old Diabetic foot ulcer grade 3 and 4 by wagner classification plt count more than 100000 in the time of intramuscular injection

Intervention groups

Within 72 hours of hospitalization, one group will be treated with weekly vitamin D 50,000 pearl, with the first tablet provided to the patient upon admission and the remaining tablets consumed after one week. This process will continue for three weeks. The second group will receive a single dose of 300,000 units of intramuscular vitamin D.

Main outcome variables

Total Antioxidant Capacity; Malondialdehyde level; Nitric oxide level; Erythrocyte Sedimentation Rate; C-Reactive Protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241215064055N1**

Registration date: **2024-12-20, 1403/09/30**

Registration timing: **prospective**

Last update: **2024-12-20, 1403/09/30**

Update count: **0**

Registration date

2024-12-20, 1403/09/30

Registrant information

Name

rozita salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3343 7522

Email address

www.rozita.salehi@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-04, 1403/10/15

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the high dose and conventional regimen of vitamin D effect on antioxidant markers of patients with diabetic foot ulcer

Public title

Comparison of the high dose and conventional regimen of vitamin D effect on antioxidant markers of patients with diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

plasma calcium level less than 10 vitamin D level in between 20-30 ng/ml age more than 18 years old Diabetic foot ulcer grade 3 and 4 by wagner classification Obtaining informed consent from patients platelet count more than 100000

Exclusion criteria:

Sensitivity to vitamin D products Known diseases associated with hypercalcemia Pregnancy and breastfeeding Primary hyperparathyroidism Patients undergoing treatment with chemotherapy or radiotherapy Use of medications that interfere with wound healing, such as: chronic use of corticosteroids (minimum equivalent dose of 40 mg of prednisone), mycophenolate, cyclosporine, tacrolimus, rituximab. Patients with severe renal failure, GFR less than 30 mL per minute. Platelet count less than 100,000, in the time of intramuscular injection of the ampoule. Hospitalization for diabetic foot ulcers in the past month Administration of injectable antibiotics for diabetic foot ulcers in the past month. Stenosis and severe occlusion of the lower limb vessels based on vascular ultrasound. Chronic alcohol consumption of more than 250 cc daily. Presence of other concurrent disorders or infections.

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

50 patients will be individually divided into two groups using the Block randomization method based on numbers generated by the random allocation software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee/Working Group in Research at Imam Khomeini Educational and Medical Center - Urmia U

Street address

Imam Khomeini Hospital, Ershad Blvd

City

Urmia

Province

West Azarbaijan

Postal code

8135157157

Approval date

2024-10-23, 1403/08/02

Ethics committee reference number

IR.UMSU.HIMAM.REC.1403.098

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

diabetic foot ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

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

Total Antioxidant Capacity

Timepoint

Before the intervention and 21 days after the intervention

Method of measurement

Based on the kit used in the laboratory

2**Description**

Blood Malondialdehyde Level

Timepoint

Before the intervention and 21 days after the intervention

Method of measurement

Based on the kit used in the laboratory

3

Description

Blood Nitric Oxide Level

Timepoint

Before the intervention and 21 days after the intervention

Method of measurement

Based on the kit used in the laboratory

4

Description

Maximum Erythrocyte Sedimentation Rate (ESR) level in Millimeters per Hour

Timepoint

Before the intervention and 21 days after the intervention

Method of measurement

Based on the kit used in the laboratory

5

Description

The highest concentration of C-reactive protein (CRP) in blood is measured in milligrams per liter.

Timepoint

Before the intervention and 21 days after the intervention

Method of measurement

Based on the kit used in the laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First (Recipients of three doses of 50,000 IU vitamin D pearls)

Category

Treatment - Drugs

2

Description

Intervention group: Second (Recipients of a single dose of 300,000 IU vitamin D injection)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Rozita Salehi Sadaqiani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Mr. Saber Qolizade, Research Vice President of Urmia University of Medical Sciences

Street address

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Rozita Salehi sadaqiani

Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can potentially be shared after individuals are made unidentifiable.

When the data will become available and for how long

Access begins 6 months after the publication of results.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

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From where data/document is obtainable

Email address: Rozita.salehi@ymail.com

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

The applicant must state the reason for their need for the data and how they will use the data via email. The result will be communicated to them within a week.

Comments