Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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
Street address
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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
No 288, Imam Ali Blvd
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5719633333
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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
Internal Medicine
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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
.
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