Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effect of two different doses of vitamin d injection supplements on foot ulcer status in type II diabetic patients with vitamin d deficiency

Protocol summary

Summary

The objective of the present randomized controlled trial is to assess the effect of vitamin D injection on foot ulcer status in type 2 diabetic patients with vitamin d deficiency . At first foot ulcer was judged with the wager scale .Subjects with Wagner lower than 2 were included and their serum: D3, FBS , ESR ,WBC, CRP and foot scale were measured.50 Subjects assigned to 2 groups. group:A Received 300.000IU and group:B 150.000 IU vitamin D injection .After 4 week all tests were done to determine the effect of vitamin D injection on diabetic foot ulcer status in subjects have vitamin D deficiency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041321740N1**
Registration date: **2015-05-16, 1394/02/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Mohsen Haratian

Name of organization / entity

Shahid sadoughi university of medical sciences and health services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2015-03-17, 1393/12/26

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of two different doses of vitamin d injection supplements on foot ulcer status in type II diabetic patients with vitamin d deficiency

Public title

Effect of vitamin d injection supplements on foot ulcer status in type II diabetic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: patients with diabetic foot ulcers; Exclusion criteria: pregnancy; presence of associated autoimmune disease; use of anti convulsants (which alter the metabolism of vitamin D); concomitant osteomyelitis; low blood pressure; use of antibiotic in recently month; skin tumors on venous ulcers and/or lymphedema; ulcers in legs of other cause than venous insufficiency; patients with renal insufficiency; paresthesias of lower limbs and the need for surgical debridement.

Age
From **30 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Etihics-in-Research Commisson Shahid Sadoughi University of Medical Sciences and Health Services
Street address
Shahid Sadoughi University of Medical Sciences and Health Services, Institute for Reproductive Sciences, Bahonar Sq
City
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Postal code
۸۹۱۶۹۷۸۴۷۷
Approval date
2015-03-14, 1393/12/23
Ethics committee reference number
2702521/1/17/پ

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
E10, E11,
ICD-10 code description
Diabetic ulcer

Primary outcomes

1

Description
Foot ulcers scale patients
Timepoint
Before and after interventuon
Method of measurement
With Auto cad 2010

Secondary outcomes

1

Description
Serum 25(OH)D3
Timepoint
Before and after interventin(after 4 week)
Method of measurement
With kit (ng/dl)

2

Description
FBS
Timepoint
Before and after interventin(after 4 week)
Method of measurement
With kit (mg/dl)

3

Description
Serum CRP
Timepoint
Before and after interventin(after 4 week)
Method of measurement
With kit (mg/l)

4

Description
Serum WBC
Timepoint
Before and after interventin(after 4 week)
Method of measurement
With kit (micro/l)

5

Description
Serum ESR
Timepoint
Before and after interventin(after 4 week)
Method of measurement
With kit (mm/hr)

Intervention groups

1

Description
GroupA: cure with 300000IU Vit D3
Category

Treatment - Drugs

2

Description
GroupB: cure with 150000IU Vit D3
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Research center
Full name of responsible person
Mohsen Haratian
Street address
Hamedan Diabetes Research center, Emam Clinic, Mirzade Eshghi Street
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
Dr Mozaffari
Street address
Shahid Sadoughi University of Medical Sciences and Health Services, Health College
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi University of Medical Sciences and Health Services
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
Name of organization / entity
Hamedan University of Medical Sciences and Health Services
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Person responsible for updating data

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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