

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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 wagner 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.

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

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)

Phone

+98 81 3622 2958

Email address

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

Ethics-in-Research Commission 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

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

2702521/1/17/۲

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 intervention

Method of measurement

With Auto cad 2010

Secondary outcomes

1

Description

Serum 25(OH)D3

Timepoint

Before and after intervention(after 4 week)

Method of measurement

With kit (ng/dl)

2

Description

FBS

Timepoint

Before and after intervention(after 4 week)

Method of measurement

With kit (mg/dl)

3

Description

Serum CRP

Timepoint

Before and after intervention(after 4 week)

Method of measurement

With kit (mg/l)

4

Description

Serum WBC

Timepoint

Before and after intervention(after 4 week)

Method of measurement

With kit (micro/l)

5

Description

Serum ESR

Timepoint

Before and after intervention(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

Full name of responsible person

Mohsen Haratian

Position

Student in Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and
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Full name of responsible person

Dr Hassan Mozaffari khosravi

Position

Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Shahid Sadoughi University of Medical Sciences and
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Full name of responsible person

Mohsen Haratian

Position

Executive-Ms,c student in nutrition and health science

Other areas of specialty/work

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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