

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of vitamin D supplementation compared with the placebo on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with diabetic foot

Protocol summary

Study aim

The aim of this study is to determine the effects of vitamin D supplementation on metabolic profiles, inflammatory factor and biomarkers of oxidative stress in patients with diabetic foot.

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial

Settings and conduct

Sixty patients with diabetic foot of eligible and referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Patients with diabetic foot according to Wagner criteria aged 40 to 85 years will be included in this study.

Intervention groups

Patients will be assigned to receive either vitamin D supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Fasting plasma glucose, lipid profiles, inflammatory factors, oxidative stress, and mean ulcer area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201510315623N54**

Registration date: **2015-11-04, 1394/08/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-16, 1398/06/25**

Update count: **1**

Registration date

2015-11-04, 1394/08/13

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-11-01, 1394/08/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D supplementation compared with the placebo on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with diabetic foot

Public title

Effects of supplementation in the treatment of diabetic foot

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic foot ulcer Aged 40 to 85 years

Exclusion criteria:

Diabetic foot ulcer with grade 3 Pregnant and breastfeeding patients Participants who consumed vitamin D supplements during the past 3 months Anticipated changes in medications throughout the study Patients with history of diseases which influence the development of diabetic foot ulcer including chronic trauma

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either vitamin D supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shahid Beheshti Clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

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Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2015-10-28, 1394/08/06

Ethics committee reference number

IR.Kaums.REC.1394.92

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

Diabetic foot

ICD-10 code

E14.5

ICD-10 code description

With peripheral circulatory complications

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

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

2**Description**

Healing of diabetic foot ulcer

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Decrease of the wound size relative to original size: ulcer length (cm), ulcer width (cm), Ulcer depth (cm)

Secondary outcomes**1****Description**

Fasting blood sugar

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2**Description**

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

7

Description

hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

8

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

10

Description

Vitamin D

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

11

Description

HbA1c

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Biochemical kit

12

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

13

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Vitamin D capsule, 50000 IU, every 2 weeks for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule, every week for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Clinic

Full name of responsible person

Reza Razzaghi

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Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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research@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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