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

Street address
Kashan University of Medical Sciences

City
Kashan

Province
Isfehan

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
Street address
Ghotbe Ravandi Boulevard, Kashan
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8115187159
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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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8115187159
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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
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
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Web page address

Person responsible for updating data

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Full name of responsible person
Zatollah Asemi

Position
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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