

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on metabolic profiles in patients with diabetic foot ulcer

Protocol summary

Study aim

The aim of this study is to determine the effects of combined magnesium and vitamin E supplementation on metabolic profiles in patients with diabetic foot ulcer.

Design

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

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Patients with diabetic foot ulcer and aged 40 to 85 years will be included in this study. Pregnant and breastfed patients, participants who consumed magnesium, vitamin E or other antioxidative supplements during past 3 months, taking antiinflammatory agents, change in consuming medications throughout the study and patients with history of diseases which influence the development of DFU including chronic trauma, will be excluded.

Intervention groups

Patients will be assigned into two groups to receive combined magnesium and vitamin E supplements (n=30) or placebo (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: **IRCT2017090533941N21**
Registration date: **2017-11-16, 1396/08/25**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-10-20, 1396/07/28

Expected recruitment end date

2017-11-05, 1396/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on metabolic profiles in patients with diabetic foot ulcer

Public title

Effect of combined magnesium and vitamin E supplementation in treatment of diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with grade 3 diabetic foot ulcer Aged 40 to 85

Exclusion criteria:

Pregnant and breastfed patients Participants who consumed magnesium, vitamin E or other antioxidative supplements during past 3 months Taking anti-inflammatory agents Change in consuming 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 combined magnesium and vitamin E 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, Kashan 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

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2017-10-19, 1396/07/27

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.65

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E14.5

ICD-10 code description

Non-insulin-dependent diabetes mellitus and with peripheral circulatory complications

Primary outcomes

1

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

3

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

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

7

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

8

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

9

Description

LDL

Timepoint

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

Method of measurement

Enzymatic kit

10

Description

Fasting plasma glucose

Timepoint

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

Method of measurement

Enzymatic kit

11

Description

HbA1c

Timepoint

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

Method of measurement

Biochemical kit

12

Description

Magnesium

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 250 mg magnesium (21st Century, Arizona, USA) and 400 IU vitamin E (Zahravi, Tabriz, Iran) daily for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij Essence, Kashan, Iran), daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Clinic

Full name of responsible person

Zatollah Asemi

Street address

Ghotbe Ravandi Boulevard, Kashan

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81151-87159

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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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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

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person

Zatollah Asemi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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