

# 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 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

###### Email address

ostadmohammadi-vr@kaums.ac.ir

##### 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

#### City

Kashan

#### Province

Isfahan

#### Postal code

81151-87159

#### Phone

+98 31 5562 0608

#### Email

asemi\_z@kaums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Gholamali Hamidi

#### Street address

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#### Phone

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#### Email

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

Ph.D of Nutrition

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Zatollah Asemi

#### Position

Ph.D of Nutrition

#### Latest degree

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
**Position**  
Ph.D of Nutrition  
**Latest degree**  
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**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