Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Clinical trial of the effect of magnesium supplementation compared with the placebo on wound healing and metabolic profiles in patients with diabetic foot ulcer

Protocol summary

Study aim

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

Design

A parallel group, double-blind (both patients and researchers,) randomized controlled clinical trial.

Settings and conduct

Sixty patients with diabetic foot ulcer referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected. Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Naghavi Hospital affiliated to Kashan University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will assigned the participants to the numbered bottles of capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic foot ulcer and aged 40 to 85 years old. Non-inclusion criteria: pregnant and breastfed patients; taking magnesium, multivitamin-mineral and antioxidant supplements, and anti-inflammatory agents; patients with history of diseases which influence the development of DFU including chronic trauma; patients with history of diseases which influence the development of diabetic foot ulcer including chronic trauma

Intervention groups

Intervention group: Magnesium capsule, 250 mg oxide magnesium (21 century, USA), once a day, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Main outcome variables

Mean ulcer area, Markers of insulin metabolism, lipid profiles, biomarkers of inflammation; oxidative stress

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201612225623N96**
Registration date: **2017-01-02, 1395/10/13**
Registration timing: **retrospective**

Last update: **2019-11-05, 1398/08/14**
Update count: **1**

Registration date

2017-01-02, 1395/10/13

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2016-10-26, 1395/08/05

Expected recruitment end date
2016-11-24, 1395/09/04
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of magnesium supplementation compared with the placebo on wound healing and metabolic profiles in patients with diabetic foot ulcer

Public title
Effect of supplementation in treatment of patients with diabetic foot ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with diabetic foot ulcer Aged 40 to 85 years
Exclusion criteria:
Pregnant and breastfed patients Taking magnesium,multivitamin-mineral and antioxidant supplements and anti-inflammatory agents 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: **70**
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 magnesium supplements (n = 35) or placebo (n = 35). 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 Naghavi Hospital affiliated to Kashan University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will 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
Isfehan
Postal code
8115187159
Approval date
2016-10-25, 1395/08/04
Ethics committee reference number
IR.Kaums.REC.1395.74

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 (Decrease of the wound size relative to original size: ulcer length (cm), ulcer width (cm), Ulcer depth (cm))
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement

Ruler

3

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

2

Description
Glutathione
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
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

9

Description
LDL cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
HbA1c
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Biochemical kit

Intervention groups

1

Description
Intervention group: Magnesium capsule, 250 mg oxide magnesium (21 century, USA), once a day, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Reza Razzaghi
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 0026
Email
razzaghi_r@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
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 2999
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
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5562 0608
Email
asemi_r@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
81151-87159

Phone
+98 31 5546 3378

Fax

Email
asemi_z@kaums.ac.ir

Web page address

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