Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Clinical trial of the effect of magnesium supplementation compared with the placebo on carotid intima-media thickness and metabolic profiles in diabetic hemodialysis patients

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of magnesium supplementation on carotid intima-media thickness (CIMT) and metabolic profiles in diabetic hemodialysis patients.

Design

Study design: randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive magnesium supplement (n=30) or placebo (n=30).

Settings and conduct

Among diabetic hemodialysis patients referred to Yasrebi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 24 weeks after the intervention. At the beginning and the end of the intervention: 24 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic hemodialysis patients aged 18 to 80 years will be included in the study.Exclusion criteria: Patients with inflammatory and malignant diseases, taking magnesium supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to enrollment in the study, taking immunosuppressive agents

Intervention groups

Intervention group: Magnesium supplements (21st Century Pharmaceutical Company, Arizona, USA), 250 mg, one capsule for 24 weeks orally. Control group: placebo (Barij Essence, Kashan, Iran), one capsule for 24 weeks orally.

Main outcome variables

Outcomes: Carotid intima-media thickness (primary outcome) and metabolic profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

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

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090133941N19**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**

Last update: **2020-08-02, 1399/05/12**
Update count: **2**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2017-12-01, 1396/09/10
Expected recruitment end date
2017-12-10, 1396/09/19
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 carotid intima-media thickness and metabolic profiles in diabetic hemodialysis patients

Public title
Effect of magnesium supplementation in treatment of diabetic hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic hemodialysis patients Aged 18 to 80 years
Exclusion criteria:
Patients with inflammatory and malignant diseases Taking magnesium supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to enrollment in the study Taking immunosuppressive agents
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
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 (<25 and ≥25 kg/m2) and age (<50 and ≥50 y), subjects will be randomly divided into two groups to receive supplement or placebo. Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
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
2017-10-19, 1396/07/27
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.69

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease

Primary outcomes

1

Description
Mean left CIMT
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Sonography

2

Description
Maximum left CIMT
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Sonography

3

Description
Mean right CIMT
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Sonography

4

Description
Maximum right CIMT
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Sonography

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Elisa kit

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Calculation using HOMA formula

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total cholesterol
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
HDL
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Hs-CRP
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Elisa kit

7

Description
Nitric oxide
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Glutathione
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: 250 mg magnesium (21st Century Pharmaceutical Company, Arizona, USA), daily for 24 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), daily for 24 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasrebi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Ghotbe Ravandi Boulevard, Kashan
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8115187159
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+98 31 4446 0180
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asemi_r@yahoo.com

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
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8115187159
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+98 31 5554 2999
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hamidi-gh@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
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable