

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)

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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

Isfahan

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

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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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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

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