Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of magnesium supplementation on kidney function, insulin resistance and metabolic profile in patients with diabetic nephropathy

Protocol summary

Study aim
This study aimed to examine the effect of magnesium supplementation on renal function, insulin resistance and metabolic profiles in patients with diabetic nephropathy.

Design
This is a double-blind randomized clinical trial

Settings and conduct
urinary albumin to creatinine ratio (UACR) is considered as a key variable and the sample size calculated 80 persons (40 persons for control group and 40 persons for patient group). All subjects will complete 4 physical activity and 4 dietary records. Outcome measurements including metabolic, renal and inflammatory profiles will be measured at the beginning and end of the study as well as anthropometric measurements.

Participants/Inclusion and exclusion criteria
Patients aged more than 18 years old with diabetic nephropathy having Fasting Blood Sugar more than 126 milligram per deciliter and proteinuria 30-300 milligram per deciliter (micro-albuminuria) and Glomerular Filtration Rate more than 90 milliliter per minute will be chosen.

Intervention groups
Patient group will receive magnesium supplement (250 milligram) and the other group will receive placebo which is similar to the magnesium tablets in color, odor and appearance both for 12 weeks.

Main outcome variables
metabolic, renal and inflammatory profiles will be measured at the beginning and end of the study as well as anthropometric measurements.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201404271485N12**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **prospective**

Last update: **2018-01-08, 1396/10/18**
Update count: **1**

Registration date
2014-05-18, 1393/02/28

Registrant information

Name
Ahmad Esmaillzadeh

Name of organization / entity
Department of Nutrition, School of Public Health, Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 1792 2791

Email address
esmaillzadeh@hlth.mui.ac.ir

Recruitment status
Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2014-04-22, 1393/02/02

Expected recruitment end date
2015-04-22, 1394/02/02

Actual recruitment start date
2014-10-06, 1393/07/14

Actual recruitment end date
2016-04-23, 1395/02/04

Trial completion date
empty

Scientific title
Effect of magnesium supplementation on kidney function, insulin resistance and metabolic profile in patients with diabetic nephropathy

Public title
Effect of magnesium supplementation on improvement of patients with diabetic nephropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
More than 18 years old Diabetic nephropathy Blood glucose more than 126 milligram per decilite Proteinuria between 30 to 300 milligram per deciliter (micro-albuminuria) Glomerular Filtration Rate more than 90 milliliter per minute Not having hypothyroidism and hyperthyroidism; Not having any urine duct infection; Not having any feverish infection; Not using cigarette or other drugs; Not having liver disease; Not having cancer; Not having any inflammatory disease Not losing weight more than 4 kilogram during last 3 months Not using any magnesium-rich supplement
Exclusion criteria:
Changing medicine doses failure to adherence (using less than 75 percent of medicines)
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
After stratification for age, sex, type and dose of medication and BMI, subjects were randomly assigned to receive either magnesium supplements or placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo was similar in appearance (color, shape, size and packaging) with supplements. Patients were indicated by numbers for principle investigator. Supplement or placebo were handed over the participants by two other health provider not related to the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib Ave, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81745-151
Approval date
2014-04-19, 1393/01/30
Ethics committee reference number
189091

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
N08.3
ICD-10 code description
Diabetic nephropathy

Primary outcomes

1

Description
albumin to creatinine ratio (UACR)
Timepoint
Baseline, week 12
Method of measurement
Commercial kit

Secondary outcomes

1

Description
Blood Urine Nitrogen
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

2

Description
Glomerular Filtration Rate
Timepoint
Baseline, week 12
Method of measurement
commercial kits

3

Description
Proteinuria
Timepoint
Baseline, week 12
Method of measurement
Methyl benzatonium chloride method

4

Description
Fasting Blood Sugar
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

5

Description
Hemoglubin A1c
Timepoint
Baseline, week 12
Method of measurement
High-Performance Liquid Chromatography

6

Description
Serum insulin
Timepoint
Baseline, week 12
Method of measurement
Enzyme-Linked Immunosorbent Assay

7

Description
High Density Lipoprotein
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

8

Description
Low Density Lipoprotein
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

9

Description
Very Low Density Lipoprotein
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

10

Description
Triglyceride
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

11

Description
Total Cholesterol
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

12

Description
C-Reactive Protein
Timepoint
Baseline, week 12
Method of measurement
Enzyme-Linked Immunosorbent Assay

13

Description
creatinine
Timepoint
Baseline, week 12
Method of measurement
Commercial kits

Intervention groups

1

Description
Magnesium supplement, each tablet contains 250 mg magnesium oxide, 1 time a day for 12 weeks
Category
Treatment - Drugs

2

Description
Placebo, similar color, odor and appearance to magnesium supplement, 1 time a day for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan University of Medical Sciences
Full name of responsible person
Ahmad Esmaeilzadeh

Street address
College of Nutrition, Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81745-151
Phone
+98 31 3792 3151
Email
a.esmaillzadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of medical sciences
Full name of responsible person
Payman Adibi
Street address
Research Assistance, Isfahan University of Medical sciences, Av. Hezarjerib, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81745-151
Phone
+98 31 3792 3151
Email
a.esmaillzadeh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Ahmad Esmaeilzade
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
College of Nutrition, Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81745-151
Phone
+98 31 1792 2776
Fax
Email
esmaillzadeh@hlth.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Community Nutrition, School of Nutrition and Food Science, Isfahan University of Medic
Full name of responsible person
Ahmad Esmaeilzade
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
College of Nutrition, Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81745-151
Phone
+98 31 1792 2776
Fax
Email
esmaillzadeh@hlth.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
College of Nutrition, Isfahan University of Medical Sciences
Full name of responsible person
Mehdi Sadeghian

Position
Bachelor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81745-151
Phone
+31 17922720
Fax
Email
vipmaster1369@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no data sharing agreement from the related organization.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The effect of oral magnesium supplementation on micro-albuminuria and metabolic status of patients with diabetic nephropathy: a double-blind randomized controlled clinical trial The primary outcome measure only is to be shared
When the data will become available and for how long
January 2017
To whom data/document is available
for people working in academic institutions
Under which criteria data/document could be used
No other criteria are not provided.
From where data/document is obtainable
mehdisad69@gmail.com
What processes are involved for a request to access data/document
After identification of applicant validity, and getting permission from related organization, the primary outcomes will be sent.
Comments