Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigation of the Effect of magnesium oxid supplementation on gene expression levels associated with insulin, lipid and inflammatory metabolism in diabetic hemodialysis patients

Protocol summary

Study aim

The aim of this study is to determine the effects of magnesium oxid supplementation on gene expression related to insulin, lipid, and inflammation in diabetic hemodialysis patients

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive magnesium oxid supplement (n=30) or placebo (n=30).

Settings and conduct

Among Diabetic hemodialysis patients referred to Akhavan Clinic affiliated to Kashan University of Medical Sciences, 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diabetic hemodialysis patients aged 45 to 75 years. 2. No smoking 3. Moderate hypertension (systolic blood pressure: 40-160 mmHg and diastolic blood pressure: 90-100 mmHg) 4. Not taking magnesium oxide supplements for the past 3 months Exclusion criteria: 1. Patients taking antioxidant and/or anti-inflammatory supplements within 3 months prior to the intervention; 2.Hypo or hyperthyroidism 3. Specific disease leading to hospitalization 4. Hypertension (systolic blood pressure above 160 mmHg and diastolic blood pressure 100 mmHg)

Intervention groups

Intervention group: Magnesium oxid supplements (Barij Essence Co., Kashan, Iran), 250 µg, daily, for 24 weeks orally. Control group: Placebo (Barij Essence Co., Kashan, Iran), containing 100 mg of starch, daily, for 24 weeks orally.

Main outcome variables

Outcomes: Expressed levels of PPAR-γ gene (primary outcome) and gene expression related to inflammation and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190912044757N1**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **retrospective**

Last update: **2019-11-23, 1398/09/02**
Update count: **0**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Najmeh Noori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3526 8932

Email address

n.noori96@iauashkezar.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-09, 1398/04/18

Expected recruitment end date

2019-08-09, 1398/05/18

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the Effect of magnesium oxid supplementation on gene expression levels associated with insulin, lipid and inflammatory metabolism in diabetic hemodialysis patients

Public title
Effect of magnesium oxide supplementation on the gene expression associated with insulin, lipid and inflammatory metabolism in diabetic hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic Hemodialysis patients with glomerular filtration less than 10 or less than 25 ml / min with malnutrition or hyperkalemia Age 45-75 years No smoking Moderate hypertension (systolic blood pressure between 160-140 mmHg and diastolic blood pressure between 90-100 mmHg)
Exclusion criteria:
Unwillingness to participate in the study Hypothyroidism or hyperthyroidism (clinical evaluation by a specialist physician and laboratory test) Specific illness that may lead to hospitalization High blood pressure (systolic pressure above 160 and diastolic pressure above 100 mm Hg)
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Diabetic hemodialysis patient in the age range of 45-75 years
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 60 by Stat Trek software and participants will be randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Capsules with separate codes 1, 2 and 3 are provided by the Barij Essence Company for blinding the researchers and participants.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research of Islamic Azad University-Yazd Branch
Street address
Shahid Gomnam Boulevard, Yazd
City
YAZD
Province
Yazd
Postal code
8915813135
Approval date
2019-07-08, 1398/04/17
Ethics committee reference number
IR.IAU.YAZD.REC.1398.023

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Expressed levels of proliferator-activated receptor gamma (PPAR-γ) gene
Timepoint
At the beginning of the study (before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

Secondary outcomes

1

Description
Expressed levels of oxidized low-density lipoprotein (LDL-ox) gene
Timepoint
At the beginning of the study (Before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

2

Description
Expressed levels of vascular endothelial growth factor (VEGF) gene expression
Timepoint
At the beginning of the study (Before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

3

Description
Expressed levels of Transforming growth factor β (TGF-β) gene
Timepoint
At the beginning of the study (Before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

4

Description
Expressed levels of Transforming growth factor α (TGF-α) gene
Timepoint
At the beginning of the study (Before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

5

Description
Expressed levels of Interleukin-8 (IL-8) gene
Timepoint
At the beginning of the study (Before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

6

Description
Expressed levels of Interleukin-1 (IL-1) gene expression
Timepoint
At the beginning of the study (Before intervention) and after 6 months of intervention
Method of measurement
Reverse Transcriptase polymerase chain reaction (RT-PCR) technique

Intervention groups

1

Description
Intervention group: administration of magnesium oxide (Barij Essence Co. Kashan, Iran), 250 mg, daily, for 24 weeks, orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), containing 100 mg of starch, daily, for 24 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Clinic, Akhavan Hospital, Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Navid Nasiri Zadeh

Street address
Shahid Gomnam Boulevard, Yazd
City
Yazd
Province
Yazd
Postal code
8915813135
Phone
+98 35 3187 2803
Email
research@iauyazd.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

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
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Yazd
Postal code
1771844351
Phone
+98 31 5546 3378
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
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

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