Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

The effects of vitamin D supplementation compared with the placebo on gene expression related to insulin and lipid in diabetic hemodialysis patients

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on gene expression related to insulin and lipid 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 vitamin D supplement (n=30) or placebo (n=30)

Settings and conduct

Among diabetic hemodialysis patients referred to Kosar Clinic affiliated to Semnan University of Medical Sciences, Semnan, 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 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic hemodialysis patients aged 18 to 80 years old. Exclusion criteria: Taking vitamin D, antioxidant, anti-inflammatory and immunosuppressive drugs during three months before intervention.

Intervention groups

Intervention group: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) every 2 weeks, for 12 weeks orally.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180525039828N1**
Registration date: **2018-08-15, 1397/05/24**
Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**
Update count: **1**

Registration date

2018-08-15, 1397/05/24

Registrant information

Name

Elahe Seyed hosseini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-14, 1396/10/24

Expected recruitment end date

2018-01-30, 1396/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of vitamin D supplementation compared with the placebo on gene expression related to insulin and lipid in diabetic hemodialysis patients

Public title
Effect of vitamin D supplementation in treatment of diabetic hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diabetic hemodialysis Individuals aged 18 to 80 years old

Exclusion criteria:
Taking vitamin D, antioxidant, anti-inflammatory and immunosuppressive drugs during three months before intervention

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
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<50 and ≥50 y). Then, participants in each block will be randomly allocated into two treatment groups to take either vitamin D supplements or placebo. Randomization will be done by the use of computer softwares.

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 Akhavan clinic, who is not involved in the trial and not aware of random sequences, will be 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
2018-01-13, 1396/10/23

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.87

Health conditions studied

1

Description of health condition studied
Hemodialysis

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Expressed levels of PPAR-γ gene

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
RT-PCR

Secondary outcomes

1

Description
Expressed levels of LDLR gene

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
RT-PCR

2

Description
Expressed levels of GLUT4 gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

3

Description

Expressed levels of IRS1 gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

4

Description

Expressed levels of IRS2 gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

5

Description

Expressed levels of LP (α) gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

6

Description

Expressed levels of PDK1 gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

7

Description

Expressed levels of PI3K gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

8

Description

Expressed levels of PKC gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

RT-PCR

Intervention groups

1

Description

Intervention group: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran) every 2 weeks, for 12 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mohammd Reza Tamadon

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Amin Avenue, Gholestan Shahrak, Semnan

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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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
Associate professor
Latest degree
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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
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