

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

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 \geq 25 kg/m²) and age (<50 and \geq 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

Isfahan

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

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

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

Ph.D.

Other areas of specialty/work

Nutrition

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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