Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles in patients with diabetic hemodialysis

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on metabolic profiles in patients with diabetic hemodialysis.

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 Akhavan 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 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 will be included in the study.Exclusion criteria: Taking vitamin D, antioxidant and/or anti-inflammatory supplements, taking immunosuppressive medications within 3 months prior to the enrollment in the study.

Intervention groups

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

Main outcome variables

Outcomes: Glycemic control (primary outcomes), and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201611155623N92**
Registration date: **2016-12-21, 1395/10/01**
Registration timing: **retrospective**

Last update: **2019-09-22, 1398/06/31**
Update count: **1**

Registration date

2016-12-21, 1395/10/01

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences

Expected recruitment start date

2016-11-09, 1395/08/19

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles in patients with diabetic hemodialysis

Public title
Effect of supplementation in treatment of patients with diabetic hemodialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic hemodialysis Aged 18 to 80 years

Exclusion criteria:
Taking vitamin D,antioxidant and/or anti-inflammatory supplements Taking immunosuppressive medications within 3 months prior to the enrollment in the study

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, after balanced blocked randomisation, subjects will be allocated 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 Semnan University of Medical Sciences

Street address
Basij Blvd, Semnan

City
Semnan

Province
Semnan

Postal code
8115187159

Approval date
2016-11-08, 1395/08/18

Ethics committee reference number
IR.SEMUMS.REC.1395.144

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
Insulin resistance

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

Method of measurement
Questionnaire

2

Description
Insulin

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

Method of measurement
Elisa kit

Secondary outcomes

1

Description
Triglycerides

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

Method of measurement
Enzymatic kit

2

Description
Total cholesterol

Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

9

Description
Creatinine
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
BUN
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

11

Description
Albumin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

12

Description
TIBC
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Vitamin D supplements (Zahravi, Tabriz, Iran), 50000 IU, every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), every 2 weeks, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Akhavan Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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8115187159
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asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Semnan University of Medical Sciences
Full name of responsible person
Ali Rashidipour
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Basij Blvd, Semnan
City
Semnan
Province
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+98 31 5546 3378
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Rashidipour-a@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Semnan 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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Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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