

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Randomized, double blinded, case-control clinical trial on effect of vitamin D supplementation on metabolic profiles in diabetic Hemodialysis patients

Protocol summary

Summary

Objectives Aim of this study is to determine the effects of vitamin D supplementation on lipid profiles, insulin sensitivity, inflammatory and stress oxidative biomarkers in diabetic hemodialysis patients. Inclusion and Exclusion Criteria Diabetic hemodialysis patients with glomerular filtration rate less than 10 ml per minute, or less than 25 ml per minute with malnutrition or hyperkalemia will enroll. All patients with overt diabetes mellitus, smoking, hypo or hyperthyroidism, any condition that need to hospitalization and hypertension (systolic pressure higher than 160 and diastolic pressure of 100 mm Hg) exclude from the study. Patients and Sample Size Seventy diabetic hemodialysis patients enroll in is a case-control, double blinded, randomized clinical trial, Phase 3, after informed consent and are randomly divided into two groups, and then interventions will conduct. Interventions In the intervention group, patients will receive pearl of vitamin D, 50000 IU weekly for 12 weeks. The control group will receive placebo for 12 weeks. Main outcome variables The main outcome variables are insulin metabolism markers, lipid profiles, inflammatory bio-markers and oxidative stress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040924625N4**
Registration date: **2017-05-11, 1396/02/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-11, 1396/02/21

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Semnan University of Medical Sciences and Health Services

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-04-03, 1397/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, double blinded, case-control clinical trial on effect of vitamin D supplementation on metabolic profiles in diabetic Hemodialysis patients

Public title

The effect of vitamin D supplementation in diabetic dialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Hemodialysis patients with malnutrition

or hyperkalemia; Diabetes mellitus. Exclusion criteria:
Overt Diabetes; Smoking; Hypothyroidism or
hyperthyroidism; Any disease that need to
hospitalization; Hypertension

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Basidj Boulevard

City

Semnan

Postal code

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

vitamin D supplementation in hemodialysis

ICD-10 code

Z49.0

ICD-10 code description

Preparatory care for dialysis

Primary outcomes

1

Description

insulin metabolism markers

Timepoint

At the first and end of study (3 months period)

Method of measurement

Laboratory tests and mathematical calculations

Secondary outcomes

1

Description

oxidative stress

Timepoint

At the first and end of study (3 months period)

Method of measurement

Laboratory tests

2

Description

inflammatory biomarkers

Timepoint

At the first and end of study (3 months period)

Method of measurement

Laboratory tests

3

Description

lipid profiles

Timepoint

At the first and end of study (3 months period)

Method of measurement

Laboratory tests

Intervention groups

1

Description

The intervention group will receive pearl of vitamin D, 50000 IU weekly for 12 weeks. Patients encourage to do not change their normal physical activity in this period.

Category

Treatment - Drugs

2

Description

The intervention group will receive placebo pearl similar to vitamin D pearl for 12 weeks. Patients encourage to do not change their normal physical activity in this period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhevan Hospital

Full name of responsible person

De. Ali Reza Soleymani

Street address**City**

Kashan

2

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Dr. Mohammad Reza Tamadon

Street address**City**

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Asgari

Street address

Basidj Boulevard

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Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Tamadon

Position

Nephrologist

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Contact

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Dr Mohammad Reza Tamadon

Position

Nephrologist

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Name of organization / entity

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Mehrdad Zahmatkes

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Researchman

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty