

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamin D supplementation on metabolic, oxidant, inflammatory indices, sirtuin-1 and irisin in type 2 diabetic patients

Protocol summary

Summary

This is a clinical, randomized and double blind trial which aims to determine the effect of vitamin D supplementation on metabolic, oxidant, inflammatory indices, sirtuin-1 and irisin in type2 diabetic patients. After obtaining the informed consents, the researchers invite 90 male and female suffering from type2 diabetes aged 25 to 65 years in accordance with the inclusion criteria (serum 25 hydroxy vitaminD3 less than 30 ng/ml, body mass index between 25 up to 35 kg/m² and HbA1c level of less than 8.5%) and exclusion criteria (insulin, pregnancy and lactation; the subjects' levels of triglyceride more than 250 mg/dl and cholesterol more than 300 mg/dl), they are invited from Besat Diabetic Clinic, Rasht and randomly divided into two intervention and placebo groups. The intervention group will use pearl of 50,000IU of vitaminD3 every week and the placebo group will have edible paraffin similar to vitaminD3 for 8 weeks. At the beginning and end of the study, metabolic (Fasting blood sugar and glycosylated hemoglobin, reactive C peptide and lipid profile), oxidant (red blood cells Gpx and SOD), inflammatory (hsCRP, ESR) indices, serum levels of 25 hydroxyvitaminD3, sirtuin-1 and irisin, Insulin sensitivity and insulin resistance will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604202365N11**

Registration date: **2016-08-21, 1395/05/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-21, 1395/05/31

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8670 4734

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Iran University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on metabolic, oxidant, inflammatory indices, sirtuin-1 and irisin in type 2 diabetic patients

Public title

The effect of vitamin D on metabolic disorders in diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes type2 in both sexes; 25 to 65 years; Serum 25 hydroxy vitaminD3 levels less than 30

nano grams per milliliter (ng/ml); Body mass index (BMI) between 25 to 35 kilograms per square meter (kg/m²); glycated hemoglobin (HbA1c) level less than 8.5%; Willingness to participate in the project Exclusion criteria: Insulin consumption; Smoking or drinking alcohol at least once a week; Regular consumption of (at least once a week) herbal, antioxidant, multivitamin mineral, vitaminD3 and omega3 supplements; Taking birth control pills and Nonsteroidal antiinflammatory drugs (NSAIDs) in the last three months; Pregnancy and lactatin; Diagnosed diseases such as cancer, digestive diseases, liver and kidney diseases, autoimmune diseases, inflammation, hypothyroidism, polycystic ovarian syndrome; Changing usual and balanced diet with vegetarian diets or single product or any other unusual changes in the last three months; triglyceride levels more than 250 Milligrams per deciliter (mg/dl) and cholesterol more than 300 mg/dl; Exposure to sun and use of solarium for tanning up to 3 months before the start of the study; Taking medications affecting vitaminD3 metabolism such as Antiepileptic drugs and corticosteroids; Consuming less than 90% of supplements; Suffering from any acute illness; Any change in the type and amount of blood glucose lowering drugs

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The subjects will randomly assigned, through permuted blocked randomization (size=4)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Hemat Express Way, Iran University of Medical Sciences, School of Health, International Campus

City

Tehran

Postal code

Approval date

2016-08-09, 1395/05/19

Ethics committee reference number

IR.IUMS.REC.1395.9223475201

Health conditions studied

1

Description of health condition studied

diabetes mellitus type2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Sirtuin-1

Timepoint

Before and 8 weeks after intervention

Method of measurement

Laboratory Kit

2

Description

Irisin

Timepoint

Before and 8 weeks after intervention

Method of measurement

Laboratory Kit

3

Description

Insulin resistance

Timepoint

Before and 8 weeks after intervention

Method of measurement

HOMA-IR formula

4

Description

HbA1C

Timepoint

Before and 8 weeks after intervention

Method of measurement

Laboratory Kit

Secondary outcomes

1

Description

C reactive peptide

Timepoint

Before and 8 weeks after intervention

Method of measurement

laboratory Kit

2

Description

Oxidant indices

Timepoint

Before and 8 weeks after intervention

Method of measurement

laboratory Kit

3

Description

25 hydroxyvitaminD3

Timepoint

Before and 8 weeks after intervention

Method of measurement

laboratory Kit

4

Description

Fasting Insulin

Timepoint

Before and 8 weeks after intervention

Method of measurement

laboratory Kit

5

Description

Lipid profile

Timepoint

Before and 8 weeks after intervention

Method of measurement

laboratory Kit

6

Description

Inflammatory indices

Timepoint

Before and 8 weeks after intervention

Method of measurement

laboratory Kit

Intervention groups

1

Description

pearl of VitaminD3 50000IU weekly for 8 weeks

Category

Prevention

2

Description

Placebo of edible paraffin and similar to vitaminD3

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat diabetes clinic in Rasht

Full name of responsible person

Mohammad reza vafa

Street address

School of Public, Iran University of Medical Sciences,
Hemat Express Way, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International vice Chancellor for research of Iran
University of Medical Sciences

Full name of responsible person

Dr Farhad Ahmadi

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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

International vice Chancellor for research of Iran
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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Professor

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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