Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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

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Mohammad Reza Vafa
Name of organization / entity
Iran University of Medical Sciences
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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 antiiflammatory 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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International Vice Chancellor for research of Iran University of Medical Sciences, Hemat Express Way,Tehran
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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
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Position
Professor

Other areas of specialty/work

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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