

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Assessment the effect of Vitamin D supplementation on insulin resistance and Adiponectin levels in patients with Diabetes Mellitus type 2

Protocol summary

Summary

Studies show that low vitamin D and Adiponectin levels are common in diabetic patients. In addition, low levels of vitamin D and Adiponectin are associated with increased cardiovascular disease risk and that low vitamin D levels may increase insulin resistance. The main purpose of this study is to see whether vitamin D supplementation can improve insulin resistance and Adiponectin levels in patients with Diabetes Mellitus type2. The randomized, placebo-controlled, double-blind clinical trial will be conducted at the Endocrinology and Metabolism Research Institute of Tehran University of Medical Sciences, Tehran, Iran. All patients seen in the institute clinics with vitamin D level between 10-30 ng/ml and do not have any of the exclusion criteria will be eligible for recruitment in the study. The study participants will be randomly assigned into 2 groups for intervention to receive oral vitamin D in 50000IU or placebo per week for 8 weeks as per group allocation. Each group will comprise of 40 participants. Vitamin D levels, insulin resistance and Adiponectin levels along with the other biochemical and nutritional parameter will be measured before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052111421N2**
Registration date: **2013-06-12, 1392/03/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Kurosh Djafarian

Name of organization / entity

TUMS

Country

Iran (Islamic Republic of)

Phone

+98 88973901

Email address

kdjafarian@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of Medical Sciences

Expected recruitment start date

2013-02-01, 1391/11/13

Expected recruitment end date

2013-07-01, 1392/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of Vitamin D supplementation on insulin resistance and Adiponectin levels in patients with Diabetes Mellitus type 2

Public title

Effect of vitamin D supplementation on diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: - personal tendency to take part in the study - DM II which has been diagnosed at least one year ago or before - The onset of diabetes should be at age 30 or older. - BMI between 25 to 30 Kg/ M2 - Age: 31 to 65 years old - 25(OH) VitD serum levels between 10-30

ng/ml - Hb A1c < 8% - no history of smoking - no history of alcohol - no history of treatment with insulin - no monopose/ no pregnancy - no history of using agents interacting vit D like: corticosteroids, anti-epileptics and OCP in last 6 month - no history of using supplementary calcium and VitD in last 6 month - no history of angina pectoris, MI & CVA in last 12 months - no history of liver and kidney disease, chronic inflammatory diseases or thyroid diseases. - no history of treatment with thiasolidindions -failing to use prescribed supplementary agent on the regular program -any change in diet during the study -any change in dose and type of prescribed medication during study -lack of tendency to complete the study -any history of skeletal pain and fracture

Age

From **31 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Endocrinology and Metabolism Research Institute of
Tehran University of Medical Sciences

Street address

shariati hospital,kargar st

City

TEHRAN

Postal code

1411413137

Approval date

2013-04-17, 1392/01/28

Ethics committee reference number

EC:00

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

adiponectin

Timepoint

before and after intervention

Method of measurement

kit

2

Description

insulin resistance

Timepoint

before and after intervention

Method of measurement

Calculation

Secondary outcomes

1

Description

BMI

Timepoint

before and after intervention

Method of measurement

Calculation based on weigh and height

Intervention groups

1

Description

Intervention supplement of 50000IU vitamin d3 per week
for 8weeks

Category

Treatment - Drugs

2

Description

control:edible parafin oil as pelacebo weekly for 8weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and Metabolism Research Institute of
Tehran University of Medical Sciences

Full name of responsible person

Mr. Baziar

Street address**City**

Tehran

Email

kdjafarian@tums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mr Baziar

Position

Msc Student

Other areas of specialty/work**Street address**

School of nutrition Sciences and Dietetic

City

Tehran

Postal code**Phone**

00

Fax**Email**

nima.baziar@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Endocrinology and Metabolism Research Institute of
Tehran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research

Street address

5th floor,shariati hospital

City

tehran

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

Yes

Title of funding source

Endocrinology and Metabolism Research Institute of
Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Kurosh Djafarian

Position

Academic staff

Other areas of specialty/work**Street address**

School of Nutrition Sciences and Dietetic

City

Tehran

Postal code**Phone**

00

Fax**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Kurosh Djafarian

Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

00

Fax**Email****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