

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin D on insulin resistance of type 2 diabetic patients

Protocol summary

Summary

1- Introduction and background: It has been suggested that there is a relationship between vitamin D deficiency and glucose metabolism in type 2 diabetes. This association has not been studied in Iran so far. 2 - Objectives: we aimed to determine the effect of vitamin D on insulin resistance in patients with type 2 diabetes. The other aim was prevention of diabetes by supply vitamin D in serum. 3 - Design: randomized controlled double-blind clinical trial; the overall follow-up period was 3 months for each subject, they will be randomly divided into two groups of intervention and control. 4 - Setting and conduct: At the start of study and after 90 days all patients will be evaluated for body mass index, waist to hip ratio, blood pressure, glycosylated hemoglobin, fasting blood sugar, triglyceride, insulin, homeostasis model assessment index and 25 - hydroxy vitamin D3. 5 - Inclusion criteria: treatment with oral hypoglycemic agents, optimal control: HbA1C (<7.5%) Exclusion criteria: gross deficiency vitamin D, renal failure, uncontrolled diabetes, daily intake of multivitamins, intake of oral vitamin D in the last month or injected in the past six months, uncontrolled hypertension. 6 - The intervention group will receive one intramuscular injection of 300,000 international units of vitamin D3 and the control group will receive placebo. 7 - The main outcome (variables): 25 - hydroxy vitamin D3 level, glycemic status, insulin and homeostasis model assessment index will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT1138901221414N12**

Registration date: **2010-11-29, 1389/09/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-29, 1389/09/08

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0037

Email address

emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Endocrinology & Metabolism Research Center of Tehran
University of Medical Sciences

Expected recruitment start date

2009-10-03, 1388/07/11

Expected recruitment end date

2010-10-03, 1389/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D on insulin resistance of type 2
diabetic patients

Public title

Effect of vitamin D on insulin resistance in type 2
diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- Good control HbA1C (< 7.5%) 2- Treatment with oral hypoglycemic agents Exclusion criteria: 1- Gross vitamin D deficiency 2- Renal failure, uncontrolled diabetes 3- Using daily multivitamine 4- Using oral vitamin D (one month prior to the study) or intravenous vit D in the 6 month period before the study 5- Uncontrolled hypertension

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 & Metabolism Research Center of
Tehran University of Medical Sciences

Street address

North Karegar St., Dr.Sharati Hospital, 5th floor

City

Tehran

Postal code**Approval date**

2009-10-02, 1388/07/10

Ethics committee reference number

E- 0098

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Insulin resistance

Timepoint

90 days

Method of measurement

Blood sample & measurement of fasting blood sugar and insulin in formula hemostasis model assessment index(fasting insulin based on microinternational unit per milliliter * fasting blood sugar based on miligram per desiliter / 405)

Secondary outcomes**1****Description**

Glycemic status

Timepoint

90 days

Method of measurement

Blood sample

Intervention groups**1****Description**

Intervention group: 1 cc ampule vitamin D 300000 IU at the beginning of the study

Category

Treatment - Drugs

2**Description**

Control group: 1 cc placebo in control group at the beginning of the study

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrinology & Metabolism Research Center of
Tehran University of Medical Sciences

Full name of responsible person

Dr. Ozra Tabatabaei Malazy

Street address

North Karegar St., Dr. Sharati Hospital, 5th floor

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology & Metabolism Research Center of
Tehran University of Medical Sciences

Full name of responsible person

Dr. Ramin Heshmat

Street address

North karegar St., Dr.Shariati Hospital, 5th floor

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology & Metabolism Research Center 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Endocrinology & Metabolism Research Center of
Tehran University of Medical Sciences

Full name of responsible person

Dr.Kamran Moradzadeh

Position

Internist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Endocrinology & Metabolism Research Center of
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Full name of responsible person

Dr. Ozra Tabatabaei Malazy

Position

MD, MPH

Other areas of specialty/work

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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