

# 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

**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****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****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*