

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Effects of vitamin D and calcium supplementation on inflammatory biomarkers and adipocytokins in patients with type 2 diabetes

#### Protocol summary

##### Summary

This study has been designed to evaluate the effects of vitamin D and calcium supplementations alone and in combination on inflammatory biomarkers and adipocytokins in type 2 diabetic patients. This study is a controlled randomized trial with period of 8 weeks. 120 subjects will select from Isfahan Endocrine and Metabolism Research Center. Inclusion Criteria included more than 30 years old; not pregnant; do not use any tobacco products; do not inject insulin; not consuming any kinds of vitamin D or calcium supplement during last 8 weeks. Exclusion criteria included become pregnant and incidence of allergies. Subjects will randomly assign in to four groups. Randomization will be achieved by permuted blocks with stratification by age, sex, BMI, type of diabetes and dose of medication. Group1 will receive 50000 IU of vitamin D3 per week plus calcium placebo, group2 will received 1000 mg of calcium carbonate per day plus vitamin D placebo, group 3 will receive 50000 IU of vitamin D3 plus 100 of mg calcium carbonate per day and group four will receive calcium and vitamin D placebos. Total cholesterol, HDL, LDL, serum triglyceride, serum glucose, serum insulin, HbA1C, leptin, adiponectin and inflammatory biomarkers such as TNF-alpha, IL-6 and high sensitivity C reactive protein (hs-CRP) will be determine by taking blood samples at the baseline and at the end of intervention. Systolic and diastolic blood pressure and anthropometric measurements (height, weight, hip and waist circumferences) will be measured at the baseline and after 8 weeks of intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012072910433N1**

Registration date: **2012-08-19, 1391/05/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-08-19, 1391/05/29

##### Registrant information

###### Name

Marjan Tabesh

###### Name of organization / entity

Medical school of Isfahan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1650 1828

###### Email address

tabesh@hlth.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Medical School of Isfahan and Food security research center

##### Expected recruitment start date

2012-08-22, 1391/06/01

##### Expected recruitment end date

2013-01-20, 1391/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of vitamin D and calcium supplementation on inflammatory biomarkers and adipocytokins in patients with type 2 diabetes

##### Public title

Effects of vitamin D and calcium supplementation in type 2 diabetic patient

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: more than 30 years old; not pregnant; do not use any tobacco products; do not inject insulin; have no history of renal failure, cancer, liver diseases, thyroid diseases or any other inflammatory diseases; not using corticosteroids; have not more than 4 kilograms weight change during last 3 months; not consuming any kinds of vitamin D or calcium supplement during last 8 weeks. Exclusion Criteria: Pregnancy; Allergy, trauma or surgery.

## Age

From **30 years** old to **149 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Science

##### Street address

Hezarjerib st. Medical School of Isfahan,Iran

##### City

Isfahan

##### Postal code

#### Approval date

2012-02-20, 1390/12/01

#### Ethics committee reference number

190136

## 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

Inflammatory Biomarkers

#### Timepoint

at baseline and after 8 weeks of intervention

#### Method of measurement

Blood sample and standard methods

### 2

#### Description

Adipocytokins including Adiponectin and Leptin

#### Timepoint

at baseline and after 8 weeks of intervention

#### Method of measurement

Blood sample and standard methods

## Secondary outcomes

### 1

#### Description

Antropometric Measurments( height, weight,hip and waist circumferences)

#### Timepoint

at the baseline and after 8 weeks of intervention

#### Method of measurement

height, hip and waist circumferences in cm and weight in kg by standard methods

### 2

#### Description

Blood pressure

#### Timepoint

at the baseline and after 8 weeks of intervention

#### Method of measurement

mmHg

## Intervention groups

### 1

#### Description

50000 IUvitamin D3 per week plus calcium placebo for 8 weeks

#### Category

Other

### 2

#### Description

1000 mg calcium carbonate per day plus vitamin D3 placebo for 8 weeks

**Category**

Other

**3****Description**

50000 IU vitamin D3 per week plus 1000 mg calcium carbonate per day for 8 weeks

**Category**

Other

**4****Description**

vitamin D3 and calcium placebos for 8 weeks

**Category**

Placebo

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

Isfahan Endocrine and Metabolism Research Center

**Full name of responsible person****Street address****City**

Isfahan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Isfahan University of Medical Science

**Full name of responsible person**

Ahmad Esmailzadeh

**Street address**

Hezarjerib st. Mdical school of Isfahan,

**City**

Isfahan

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

Yes

**Title of funding source**

Isfahan University of Medical Science

**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**

Isfahan University of Medical Science

**Full name of responsible person**

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**Position**

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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*