

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### The effect of Vit-D on adiponectin plasma levels and insulin resistance in first-degree relatives of diabetic patients

#### Protocol summary

##### Summary

The objective of this randomized, not blinded trial is to investigate the effect of Vit D on adiponectin plasma levels in first-degree relatives of diabetic patients. In this study, 64 first-degree relatives of diabetic patients who meet the inclusion/exclusion criteria will be recruited and randomly assigned into the intervention or control group. The participants in the intervention group will receive 50000 IU Vit D weekly for 12 weeks. The participants in the control group will receive no intervention. We recommend regular exercise and weight control in the two groups. Fasting blood glucose, 2 hours post prandial glucose, triglyceride, cholesterol, LDL, HDL, insulin, HOMA Index and adiponectin will be measured before and after the intervention and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105176430N1**

Registration date: **2011-07-26, 1390/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-07-26, 1390/05/04

##### Registrant information

##### Name

Seyed Mohammad Mohammadi-zarch

##### Name of organization / entity

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1522 3999

##### Email address

m\_mohammadi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

##### Expected recruitment start date

2010-04-21, 1389/02/01

##### Expected recruitment end date

2010-07-23, 1389/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Vit-D on adiponectin plasma levels and insulin resistance in first-degree relatives of diabetic patients

##### Public title

The effect of Vit-D on adiponectin plasma levels and insulin resistance in first-degree relatives of diabetic patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: First-degree relatives of diabetic patients; BMI >25kg/m<sup>2</sup>; age between 25-65 years.  
Exclusion criteria: Diabetic patients; who has consumed Vit-D supplementation or Metformin for past three months.

##### Age

From **25 years** old to **65 years** old

##### Gender

Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Shahid Sadoughi University of Medical sciences

**Street address**  
Bahonar Square

**City**  
Yazd

**Postal code**  
8916978477

**Approval date**  
2010-03-13, 1388/12/22

**Ethics committee reference number**  
118101/1/17/پ

## Health conditions studied

### 1

**Description of health condition studied**  
First degree Relatives of Diabetic Patients

**ICD-10 code**  
E10, E11,

**ICD-10 code description**  
Diabetes mellitus

## Primary outcomes

### 1

**Description**  
Insulin

**Timepoint**  
Before intervention and 12 weeks after intervention

**Method of measurement**

Insulin Kit and the Unit is mu/lit

### 2

**Description**  
Adiponectin

**Timepoint**  
Before intervention and 12 weeks after intervention

**Method of measurement**  
Adiponectin kit and the unit is ng/ml

## Secondary outcomes

### 1

**Description**  
FBS

**Timepoint**  
12 weeks

**Method of measurement**  
Measurement of blood glucose by Auto analyzer method

### 2

**Description**  
2hpp

**Timepoint**  
12 weeks

**Method of measurement**  
Measurement of blood glucose by Auto analyzer method

### 3

**Description**  
TG

**Timepoint**  
12 weeks

**Method of measurement**  
Measurement of triglyceride by Auto Analyzer method

### 4

**Description**  
Cholesterol

**Timepoint**  
12 weeks

**Method of measurement**  
Measurement of cholestrol by Auto nalyser method

### 5

**Description**  
HDL

**Timepoint**  
12 weeks

**Method of measurement**  
Measurement of HDL by Auto Analyser method

### 6

**Description**  
LDL

**Timepoint**

12 weeks  
**Method of measurement**  
Measurement of LDL by Auto Analyser method

## Intervention groups

### 1

**Description**  
Intervention group will consume 50000 IU Vit D weekly for 12 weeks

**Category**  
Treatment - Drugs

### 2

**Description**  
Control group will receive nothing

**Category**  
N/A

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Yazd Diabetic Research Center, Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Seyed Ahmad Eghbali Zarch  
**Street address**  
Afshar Alley, Jomhouri Blvd  
**City**  
Yazd

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shahid Sadoughi University of Medical sciences, Yazd Diabetes Research Center  
**Full name of responsible person**  
Dr.Mohammad Afkhami-Ardekani  
**Street address**  
Afshar Alley, Jomhouri Blvd.  
**City**  
Yazd  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Sadoughi University of Medical sciences, Yazd Diabetes Research Center  
**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**  
Yazd Diabetes Research Center, Shahid Sadooghi University of Medical Sciences  
**Full name of responsible person**  
Seyed Ahmad Eghbali zarch  
**Position**  
Internal Medicine Resident  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

**Contact**  
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**Full name of responsible person**  
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Assistant professor of Endocrinology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd Diabetes Research Center, Shahid Sadoughi  
University of Medical Sciences

**Full name of responsible person**

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**Position**

Internal Medicine Resident

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

Yazd Diabetes Research Center, Afshar Alley,  
Jomhuri BLV., Yazd, Iran

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drc@ssu.ac.ir

**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*