Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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/m2; 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 cosume 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

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Mohammad Mohammadi Zarch

Position

Assistant professor of Endocrinology

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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