

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### The effect of zinc sulfate on plasma adiponectin 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 zinc sulfate on plasma Adiponectin and insulin resistance in first-degree relatives of diabetic patients. In this study, 70 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 50 mg zinc sulfate daily 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: **IRCT138811253312N2**

Registration date: **2011-05-24, 1390/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-05-24, 1390/03/03

##### Registrant information

##### Name

Sedigheh Soheilykhah

##### 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

s\_soheilykhah@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Yazd Diabetes Research Center, Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2009-10-12, 1388/07/20

##### Expected recruitment end date

2010-03-11, 1388/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of zinc sulfate on plasma adiponectin and insulin resistance in first-degree relatives of diabetic patients

##### Public title

The effect of zinc sulfate on plasma adiponectin and insulin resistance in first-degree relatives of diabetic patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: First-degree relatives of diabetic patients with BMI >25kg/m<sup>2</sup> and age>25 years Exclusion criteria: Diabetic patients or first degree relatives with BMI=<25kg/m<sup>2</sup> or who consumed Vit D or Magnesium supplementation for past three months

##### Age

From **25 years** old to **60 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked***No information***Sample size**Target sample size: **70****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 Sceinces

**Street address**Shahid Sadoughi University of Medical Sceinces,  
Bahonar Square, Yazd, Iran**City**

Yazd

**Postal code**

8916978477

**Approval date**

2009-04-13, 1388/01/24

**Ethics committee reference number**

118098/1/17/پ

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

First gegree 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 nalyser method

**2****Description**

2hpp

**Timepoint**

12 weeks

**Method of measurement**

Measurement of blood glucose by Auto nalyser method

**3****Description**

TG

**Timepoint**

12 weeks

**Method of measurement**

Measurement of triglyceride by Auto Analyser 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 50mg Zinc Sulfate daily for 12 weeks  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group will receive nothing  
**Category**  
Lifestyle

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Yazd Diabetic Research Center, Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Dehghan  
**Street address**  
Yazd Diabetic Research Center, Afshar Alley, Jomhuri BLV., Yazd, Iran  
**City**  
Yazd

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Yazd Diabetes Research Center, Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Sedigheh Soheilykhah  
**Street address**  
Yazd Diabetes Research Center, Afshar Alley, Jomhuri BLV., Yazd, Iran  
**City**  
Yazd  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Yazd Diabetes Research Center, Shahid Sadoughi 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**  
Yazd Diabetes Research Center, Shahid Sadoughi University of Medical Sciences  
**Full name of responsible person**  
Mohammad Reza Dehestani  
**Position**  
Internal Medicine Resident  
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## Person responsible for scientific inquiries

### Contact

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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**

Sedigheh Soheilykhah

**Position**

Assistant Professor of Internal Medicine

**Other areas of specialty/work**

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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*