

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of Sylimarin on insulin resistance and lipid profile in first-degree relatives of diabetic patients

Protocol summary

Summary

The objective of this randomized, double blinded trial is to investigate the effect of sylimarine on insulin resistance and plasma lipid profile in first-degree relatives of diabetic patients. In this study, 60 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 140 mg sylimarine twice a day for 12 weeks. The participants in the control group will receive placebo. We recommend regular exercise and weight control in the two groups. Fasting blood glucose, 2 hours post prandial glucose, triglyceride, cholesterol, LDL, HDL, insulin and HOMA Index will be measured before and after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110116430N2**

Registration date: **2011-10-17, 1390/07/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-17, 1390/07/25

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

2011-09-01, 1390/06/10

Expected recruitment end date

2011-12-01, 1390/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Sylimarin on insulin resistance and lipid profile in first-degree relatives of diabetic patients

Public title

The effect of Sylimarin on insulin resistance and lipid profile in first-degree relatives of diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: First-degree relatives of diabetic patients with BMI >25kg/m² and age>25 years and age<65 year. Exclusion criteria: Diabetic patients or first degree relatives with BMI=<25kg/m² or who consumed drug or supplementation that reduce insulin resistance for past three months.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Shahid Sadoughi University of Medical Sciences

Street address

Bahonar Square

City

Yazd

Postal code

Approval date

2011-02-21, 1389/12/02

Ethics committee reference number

126952

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

lipid profile

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Pars Azmoon kit and the Unit is mg/dl

Secondary outcomes

1

Description

TG

Timepoint

12 weeks

Method of measurement

Measurement of blood glucose by Pars Azmoon kit

2

Description

LDL

Timepoint

12 weeks

Method of measurement

Measurement of LDL by Pars Azmoon kit

3

Description

HDL

Timepoint

12 weeks

Method of measurement

Measurement of HDL by Pars Azmoon kit

4

Description

Cholesterol

Timepoint

12 weeks

Method of measurement

Measurement of cholesterol by Pars Azmoon kit

5

Description

2hpp

Timepoint

12 weeks

Method of measurement

Measurement of blood glucose by Auto nalyser method

6

Description

FBS

Timepoint

12 weeks

Method of measurement

Measurement of blood glucose by Auto nalyser method

Intervention groups

1

Description

Control group will receive placebo

Category

Placebo

2

Description

Intervention group will consume 140mg Sylimarini twice a day for 12 weeks

Category

Treatment - Drugs

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
Blvd.

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

Dr. Mohammad Mohammadi

Street address

Yazd Diabetes Research Center, Afshar Alley,
Jomhuri Blvd.

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

Saeed Bolurani

Position

Internal Medicine Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd Diabetes Research Center, Shahid Sadoughi
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Full name of responsible person

Seyed Mohammad Mohammadi Zarch

Position

Assistant professor of Endocrinology

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Seyed Mohammad Mohammadi Zarch

Position

Assistant Professor of Internal Medicine

Other areas of specialty/work

Street address

City

Postal code

Phone

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