Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 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
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 cholestrol 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 cosume 140mg Sylimarin 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, Jomhouri Blnd.
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Diabetes Research Center, Shahid Sadoughi Univercity of Medical Sciences
Full name of responsible person
Dr. Mohammad Mohammadi
Street address
Yazd Diabetes Research Center, 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
Yazd Diabetes Research Center, Shahid Sadoughi Univercity 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 Sadooghi 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 updating data

Contact
Name of organization / entity
Yazd Diabetes Research Center, Shahid Sadoughi

University of Medical Sciences

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