Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Silymarin on the level of lipid profile and fasting blood sugar and HbA1c in patients with type 2 diabetes.

Protocol summary

Study aim

The effect of Silymarin supplementation on lipid profile and fasting blood sugar and HbA1c in patients with type 2 diabetes

Design

A controlled, parallel-group, single-blind, randomized, phase II-III clinical trial in 48 patients. Using a block randomization approach.

Settings and conduct

The present study includes 48 adults with T2DM aged 30-68 years who referred to the Endocrinology and Metabolism Research Institute of Iran University of Medical Sciences in 2021.in intervention group three 140 mg pills per day were chosen as the supplementary dosage for Silymarin the control group were placed on a carbohydrate distribution diet for 12 weeks. The tablet was administered by an endocrinologist and the patient and the project's executor did not know that the supplement had received Silymarin, this study was a single-blind.

Participants/Inclusion and exclusion criteria

Age group 68-30 years Fasting plasma sugar more than 126 mg/dl Duration of the onset of the disease more than 2 years exclusion criteria: Cardiovascular disease, infectious diseases, kidney disease, thyroid disease Treatment with Silymarin 30 days before study - Taking chemical drugs and herbal supplements and nutritional supplements - Insulin therapy

Intervention groups

In diabetes, Silymarin reduces plasma glucose by reducing insulin resistance and repairing beta cells in the pancreas. Each patient in the silymarin group was given 3 capsules of 140 mg silymarin daily and a carbohydrate distribution diet also the control group for 12 weeks

Main outcome variables

in both silymarin and control groups after the study, significant reduction was seen in lipid profile and glycemic index in both. However, after adjusted for physical activity, duration of diabetic, drug use no significant difference was observed between the two groups for other investigated factors after 12 weeks of intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230318057749N1**
Registration date: **2024-02-24, 1402/12/05**
Registration timing: **retrospective**

Last update: **2024-02-24, 1402/12/05**
Update count: **0**

Registration date

2024-02-24, 1402/12/05

Registrant information

Name

Samira Ferdowsi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3474 1908

Email address

samira.fer230@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

2021-12-11, 1400/09/20

Actual recruitment end date

2022-07-16, 1401/04/25

Trial completion date

2022-07-16, 1401/04/25

Scientific title

The effect of Silymarin on the level of lipid profile and fasting blood sugar and HbA1c in patients with type 2 diabetes.

Public title

The effect of Silymarin in type 2 diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes referring to the clinic of the Endocrine Research Institute of Iran University of Medical Sciences Age group 30-68 years Fasting plasma sugar more than 126 mg/dl Duration of the onset of the disease more than 2 years

Exclusion criteria:

Pregnant and lactating women People less than 30 years old Following a special diet Suffering from cardiovascular disease, infectious diseases, kidney disease, thyroid disease Treatment with Sealy Marine in 30 days before the study Using chemical drugs and herbal supplements and nutritional supplements Insulin therapy

Age

From **30 years** old to **68 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: Simple randomization is one of the most popular methods used to implement the randomization process. In this method, there is a possibility of inequality in the number of people assigned to each group, especially in studies with a small sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

First, the case of diabetic patients whose ages were between 30-68 years old was examined by visiting the clinic of the Endocrine Research Institute of Iran University of Medical Sciences and coordinating with the relevant officials. Then they were selected by simple non-probability sampling (convenience sampling). The objectives of this research were fully explained to the subjects. If they are willing to cooperate, they were asked to read and fill out a written consent form and register in the project. The researcher gave the two control and intervention groups a diet plan and Silymarin tablets were prescribed by a senior endocrinologist, and the nutritionist and the project manager did not know which person received Silymarin supplements.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Medical Sciences and Technologies, Islamic Azad University, Science a

Street address

No. 37, Shaghayegh Ave, South Shahran, Tehran

City

Tehran

Province

Tehran

Postal code

1478674871

Approval date

2021-11-30, 1400/09/09

Ethics committee reference number

IR.IAU.SRB.REC.1400.281

Health conditions studied

1

Description of health condition studied

Type 2 Diabetic

ICD-10 code

I Certain

ICD-10 code description

Chapter IV Endocrine, nutritional and metabolic diseases(E00-E90)

Primary outcomes

1

Description

lipid profile and Glycemic index

Timepoint

Measurement of lipid profile and glycemic index at the beginning of the study and after consumption of silymarin study

Method of measurement

laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Silymarin supplement use -control group: Diet intake-Type 2 diabetes patients took Silymarin supplement in the form of 140 mg capsules from Gol Daru company - 3 times a day for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Research Institute, Iran University of Medical Sciences
Full name of responsible person
Samira Ferdowsi Sochelmaei
Street address
No. 37, Shaghayegh Ave, South Shahran, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Vice President of Research and Technology, Islamic Azad University, Research Sciences Unit
Street address
At the end of Satari Highway, University Square, Hesarak Blvd., Tehran
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Phone
+98 21 4484 5205
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med@srbiau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Institute of Endocrinology and Metabolism Iran university
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Samira Ferdowsi Sochelmaei
Position
Master Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical study report-Study protocol Only part of the data, such as information related to the main outcome, can be shared.

When the data will become available and for how long

The access period begins 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers can see the main result of the study, including the results and review of the study.

From where data/document is obtainable

Phytotherapy Research Samira Ferdowsi

What processes are involved for a request to access data/document

The data will be shared after publication in the journal.

Comments