

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of silymarin on cholesterol triglyceride and BMI in patients with type 2 diabetes mellitus referring to endocrine clinic of Imam khomeini hospital Urmia

Protocol summary

Study aim

Evaluation of the effect of silymarin on cholesterol triglyceride and BMI in patients with type 2 diabetes mellitus referring to endocrine clinic of Imam khomeini hospital Urmia

Design

In this study ,50 eligible patients with type 2 diabetes mellitus referred in the endocrinology clinic of Imam khomeini Hospital of Urmia are chosen. Patients will be randomly assigned into two groups of control and intervention ,each patient will have a special code.

Settings and conduct

Patients will be randomly assigned to either intervention or control group after obtaining informed consent. The control group will receive routine oral antidiabetic drugs and placebo and the intervention group will receive common oral antidiabetic drugs and 140 mg silymarin twice a day for 12 days. The researcher and the patients will not be informed about the allocation of patients to the intervention or control groups (double blind). Patients will be evaluated at the start of the study and the second month for LDL ,HDL, triglyceride ,total cholesterol and BMI, and the results will be recorded on the relevant chart.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 30_65; diabetes diagnosis according to WHO standards (FBS>126 or 2hpp>200 or HbA1c>9%); having fasting blood sugar less than 250 mg/dl; history of diabetes mellitus more than one year; having informed consent. Exclusion criteria: insulin therapy, pregnancy and lactation; autoimmune and malignant diseases, taking medications that interfere with plasma levels of blood sugar; smoking; undergoing surgery

Intervention groups

The study will be conducted with the participation of two groups of patients with type 2 diabetes mellitus. The

intervention group who will receive the routine anti diabetic treatment with silymarin and the control group who will receive routine anti diabetic treatment with placebo.

Main outcome variables

BMI and Lipid profile

General information

Reason for update

Acronym

ULS

IRCT registration information

IRCT registration number: **IRCT20170814035697N4**

Registration date: **2019-10-06, 1398/07/14**

Registration timing: **retrospective**

Last update: **2019-10-06, 1398/07/14**

Update count: **0**

Registration date

2019-10-06, 1398/07/14

Registrant information

Name

Hamdolah Sharifi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01
Expected recruitment end date
 2019-08-21, 1398/05/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Evaluation of the effect of silymarin on cholesterol triglyceride and BMI in patients with type 2 diabetes mellitus referring to endocrine clinic of Imam khomeini hospital Urmia

Public title
 Evaluation of the effect of silymarin on cholesterol triglyceride and BMI in patients with type 2 diabetes mellitus referring to endocrine clinic of Imam khomeini hospital Urmia

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 30_65 Diagnose of diabetics according of WHO criteria FBS >126 mg/dl or 2hpp>200 mg/dl or HbA1c>9% A history of DM is more than 1 year old FBS<250 Conscious informed consent to participate in the study
Exclusion criteria:
 Insulin therapy for autoimmune diseases and cancer Taking drugs that interfere with the level of plasma glucosesmoking Smoking Pregnancy and lactationcatching Hospitalized or undergoing surgery

Age
 From **30 years** old to **65 years** old

Gender
 Both

Phase
 1-2

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The randomization method is that 46 letters A and 46 B characters are poured into a bag, and if a sample is chosen, a number is randomly taken out of the bag. If the letter A is the group receiving the silymarin, and if the letter B The control group was identified

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In this study, the patient, the person who performed the project, the relevant guidance teachers, and the patient's blind physician were kept so that none of them is aware of the type of drug (silymarin or placebo) by the

patient.
Placebo
 Used
Assignment
 Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences;Resalat Ave;Jahad Blvd;Urmia;West Azerbaijan Province;Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-04, 1397/09/13

Ethics committee reference number

332.lr.umsu.rec.1397

2

Ethics committee

Name of ethics committee

Uremia University of Medical Sciences

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Orjhans Alley , Resalat Blvd,Urmia,Iran

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Urmia

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West Azarbaijan

Postal code

571483734

Approval date

2018-12-04, 1397/09/13

Ethics committee reference number

lr.umsu.rec.1397.

Health conditions studied

1

Description of health condition studied

BMI and Lipid profile in type 2 DM

ICD-10 code

ICD-10 code description

R4

Primary outcomes

1

Description

Lipid profile

Timepoint

Before and after of treatment

Method of measurement

Lab data

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: routin treatment +livergol tablets with a dose of 40 mg ,BID ,daily for patients with type 2 DM

Category

Treatment - Drugs

2

Description

Control group:routin anti diabetes treatment with placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam khomeini Hospital

Full name of responsible person

Hamdolah Sharifi

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Imam Khomeini hospital;Ershad Ave;Modarres Blvd;Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Hamdolah Sharifi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Other areas of specialty/work

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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