Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of silymarin on blood sugar profile(FBSand 2hpp) and HbA1C in patients with type 2 diabetes mellitus

Protocol summary

Study aim

Evaluation of the effect of silymarin on Blood glucose profiles(FBS ,2hpp) and HbA1C 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 refferd 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 FBS,2hpp and HbA1c 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>126or2hpp>200orHbA1c>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 ,therapy;pregnancy and lactation;having diseases of autoimmune and cancer;taking medication that interfere with plasma levels of blood sugar;smoking;hospitalization or undergoing surgery

Intervention groups

The study will be conducted with the participiation of two groups of patients with type 2 diabetes mellitus.The intervention group,which will receive the anti_diabetic treatment with silymarin and the control group,will receive a commen treatment with placebo

Main outcome variables

Blood glucose profiles

General information

Reason for update

Acronym

UGS

IRCT registration information

IRCT registration number: **IRCT20170814035697N5**
Registration date: **2019-12-16, 1398/09/25**
Registration timing: **retrospective**

Last update: **2019-12-16, 1398/09/25**
Update count: **0**

Registration date

2019-12-16, 1398/09/25

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

2019-04-06, 1398/01/17

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of silymarin on blood sugar profile(FBSand 2hpp) and HbA1C in patients with type 2 diabetes mellitus

Public title

Evaluation of the effect of silymarin on blood sugar profile(FBSand 2hpp) and HbA1C in patients with type 2 diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 30-65 diagnose of diabetics according to WHO criteria FBS>126mg/dl or 2HP>200mg/dl or HbA1c>9% fasting blood glucose less thanmg/dL 250 A history of diabetes is more than 1 year old Conscious informed consent to participate in the study

Exclusion criteria:

Insulin therapy Pregnancy and lactation catching for autoimmune diseases and cancer Taking drugs that interfere with the level of plasma glucose smoking 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 50 letters A and 50 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

Parallel

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 Azerbijan Provine;Iran

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urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.UMSU.REC.1397.331

Health conditions studied

1

Description of health condition studied

Blood glucose profiles in patients with type 2 diabetes

ICD-10 code

R73

ICD-10 code description

Elevated blood glucose level

Primary outcomes

1

Description

Blood glucose profiles

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 140 mg ,BID ,daily for patients with type 2 DM

Category

Treatment - Drugs

2

Description
Control group: routin anti diabetes treatment with placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Urmia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
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Urmia University of Medical Sciences
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Person responsible for updating data

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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