# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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

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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

**City**

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**

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**Name of organization / entity**
Oroumia University of Medical Sciences
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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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## 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