# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## The effects of Silybum marianum (L.) Gaertn. (Silymarin) supplement consumption on metabolic status, Hs-CRP and oxidative stress in type 2 diabetic patients with overweight or obesity

## Protocol summary


**Summary**

(1) Objectives: In this study diabetic patients will be assessed in order to determine the effects of Silybum marianum (Silymarin) supplement consumption on metabolic status, Hs-CRP and oxidative stress in type 2 diabetic patients with overweight or obesity. (2) Design: This study will be conducted as a randomized controlled trial. (3) Setting and conduct: Subjects were randomly divided into two groups including 20 subjects (taking Silybum marianum extract (silymarin)) and control (placebo). For each patient anthropometric measurements (height, weight and BMI) will be assessed and general characteristics and 24-h food record questionnaire in order to assessment of food intake for 3 days a week at the baseline and end of the study will be filled. 8 cc fasting blood samples from each patient will be taken at the beginning and end of the intervention. (4) Participants including major eligibility criteria: Inclusion criteria consists of: At least 6 months history of diabetes; usage of blood sugar lowering drugs; age between 20 and 50 years old and Exclusion criteria are: Pregnancy; lactation; kidney; heart and inflammatory disease. (5) Intervention: Intervention groups will receive daily 3 tablets which each tablet contain 140 milligrams of silymarin with meal and control group use the same amount placebo tablets daily for 45 days. (6) Main outcome measures (variables): Fasting blood glucose levels, fasting serum insulin, insulin resistance, serum lipids, Hs-CRP and Indicators of oxidative stress including total antioxidant capacity, malondialdehyde, glutathione peroxidase and superoxide dismutase in both groups before and after the intervention will be measured.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201309243140N13**
Registration date: **2013-11-16, 1392/08/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2013-11-16, 1392/08/25


**Registrant information**

**Name**

Bahram Pourghassem Gargari

**Name of organization / entity**

Health and Nutrition Faculty, Tabriz University of medical sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice chancellor for Research, Tabriz University of Medical Sciences


**Expected recruitment start date**

2013-10-23, 1392/08/01

**Expected recruitment end date**

2013-12-22, 1392/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
The effects of Silybum marianum (L.) Gaertn. (Silymarin) supplement consumption on metabolic status, Hs-CRP and oxidative stress in type 2 diabetic patients with overweight or obesity

**Public title**
The effects of Silybum marianum (L.) Gaertn. (Silymarin) supplement consumption on metabolic status, Hs-CRP and oxidative stress in type 2 diabetic patients with overweight or obesity

**Purpose**
Supportive

**Inclusion/Exclusion criteria**
Inclusion criteria: Type 2 diabetes for at least 6 months; age between 20-50 (both of gender) years and usage of blood glucose lowering drugs. Exclusion criteria: usage of nutritional supplements in the past 3 months or during the study; usage of insulin; Pregnancy or lactation; BMI more than 35 and lower than 27; Renal and liver failure; Cardiovascular disease; Thyroid disorders; History of allergy; Smoking; Alcohol usage; Following a specific diet; Taking corticosteroids or Immunosuppressive drugs,...

**Age**
From **20 years** old to **50 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Tabriz University of Medical Sciences

**Street address**
Tabriz University of Medical Sciences, Golbad Street

**City**
Tabriz

**Postal code**

**Approval date**
2013-09-10, 1392/06/19

**Ethics committee reference number**
9289

## Health conditions studied

### 1

**Description of health condition studied**
Type 2 diabetes

**ICD-10 code**
E10,E11,E1

**ICD-10 code description**
Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

**Description**
Fasting blood glucose

**Timepoint**
Baseline and after 45 days of intervention

**Method of measurement**
Enzymatic colorimetric

### 2

**Description**
Insulin resistance

**Timepoint**
Baseline and after 45 days of intervention

**Method of measurement**
HOMA-IR calculation

### 3

**Description**
Fasting insulin serum

**Timepoint**
Baseline and after 45 days of intervention

**Method of measurement**
ELISA assay

### 4

**Description**
Lipid profiles (TC, TG, LDL-C, HDL-C)

**Timepoint**
Baseline and after 45 days of intervention

**Method of measurement**
Enzymatic methods for TC,TG and HDL-C For LDL-C : Freidwald's formula: LDL-C = TC- HDL-C - (TG/5)

### 5

**Description**
Hs-CRP

**Timepoint**
Baseline and after 45 days of intervention

**Method of measurement**
immunoturbidimetry

**6**

**Description**
serum malondialdehyde (MDA)
**Timepoint**
Baseline and after 45 days of intervention
**Method of measurement**
spectrophotometry

**7**

**Description**
serum total antioxidant capacity
**Timepoint**
Baseline and after 45 days of intervention
**Method of measurement**
spectrophotometry

**8**

**Description**
GPX activity
**Timepoint**
Baseline and after 45 days of intervention
**Method of measurement**
spectrophotometry

**9**

**Description**
SOD activity
**Timepoint**
Baseline and after 45 days of intervention
**Method of measurement**
spectrophotometry

## Secondary outcomes

**1**

**Description**
calorie and nutrients intake
**Timepoint**
before and after 45 dyas intervention
**Method of measurement**
24-h recall Questionnaire

**2**

**Description**
Anthropometric index(weight, height,WHR and Body Mass
**Timepoint**
before and after 45 days intervention
**Method of measurement**
Analogue scale for weight and weight(Kg)/Square Height for body mass index

**3**

**Description**
systolic and diastolic blood pressure
**Timepoint**
before and after 45 days intervention
**Method of measurement**
standard barometer

## Intervention groups

**1**

**Description**
Intervention group will receive daily 3 tablets of silymarin with meal for 45 days (each tablets of silymarin contains 140 milligrams pure silymarin). silymarin tablets will be purchased from the Livergol ®; Goldaru Herbal Products Pharmaceutical Company. All the patients will receive the tablets on every two weeks base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews and 2-weeks check lists.
**Category**
Treatment - Drugs

**2**

**Description**
The control group will receive daily 3 tablets of placebo with meal for 45 days. (Placebo tablets will be produced at the faculty of pharmacy of Tabriz University of medical sciences).
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
East Azerbayjan Diabetes Society
**Full name of responsible person**
Soraiya Ebrahimpour Koujan
**Street address**
East Azerbayjan Diabetes Society, Near Haj Ali Asghar Nazir Vand mosque, 24 yards Fatemi Street, North Ghatran Street
**City**
Tabriz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for Research, Tabriz University of Medical Sciences
**Full name of responsible person**
Seyed Kazem Shakouri

**Street address**
Tabriz University of Medical Sciences, Golbad Street
**City**
Tabriz
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for Research, Tabriz University 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**
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## Person responsible for scientific inquiries

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## 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*