Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Name of organization / entity
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Person responsible for updating data

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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