Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Effects of hydro-alcoholic artichoke leaf extract supplementation on metabolic and antioxidant status in patients with metabolic syndrome with regard to genetic polymorphism of CETP, TCF7L2 and FTO

Protocol summary

Summary

This study is a double blind randomized clinical trial that aims in determining the effects of hydro-alcoholic artichoke leaf extract supplementation on metabolic and antioxidant status with regard to genetic polymorphism of CETP, TCF7L2 and FTO. It will be examined on 80 patients with metabolic syndrome. Blinding will be performed on patients and measuring the outcomes of study (researchers). At first the volunteers in the study will be observed in respect to inclusion criteria and qualified individuals will be asked to sign a written agreement. Venus blood samples of candidates will be collected and evaluated after 10-12 hours of fasting in respect of serum sugar and lipids. Also anthropometric measurements and blood pressure will be performed. Later, infected individual will be found out. In two groups they will be allocated in quadruple blocks: 1) supplement (daily intake of 1800 milligrams hydro-alcoholic artichoke leaf extract in the form of 4 tablets), 2)placebo (daily intake of 1800 milligrams placebo in the form of 4 tablets containing corn starch, lactose and avicel). Candidates will be requested to take one tablet before breakfast, 2 tablets before lunch and one tablet before dinner for the period of three months. Serum amount of sugar, lipid, insulin, CETP, total antioxidant capacity and MDA will be measured before and after intervention. Desired gens' polymorphism will be determined based on RFLP-PCR method. The amount of food intake will be studied by using 3-days food-recall questionnaire, accompanying with anthropometric measurements and physical activity every 45 days as probabilistic confounder agents.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409033320N9**

Registration date: **2014-12-27, 1393/10/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-27, 1393/10/06

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of hydro-alcoholic artichoke leaf extract supplementation on metabolic and antioxidant status in patients with metabolic syndrome with regard to genetic polymorphism of CETP, TCF7L2 and FTO

Public title

Effects of hydro-alcoholic artichoke leaf extract supplementation on metabolic and antioxidant status in patients with metabolic syndrome with regard to genetic polymorphism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness and ability to collaborate on project ; aged between 20-60 years (both sexes); affected by metabolic syndrome: having at least 3 of 5 criteria according to international definition: waist circumference >91 cm in women and >89cm in men, serum glucose ≥100 mg/dl, serum triglyceride ≥150 mg/dl, HDL-C >40 mg/dl in men and >50 mg/dl in women, systolic blood pressure ≥ 130 mmHg and/or diastolic blood pressure ≥ 85 mmHg Exclusion criteria: Smoking ; Consumption of fish oil supplement or other antioxidant supplements currently or within 3 months before intervention; Consumption of lipid or blood pressure lowering drugs, corticosteroids currently or within 3 months before intervention; affected by cardiovascular disease, renal failure, diabetes mellitus, liver dysfunction, cancer; affected by Infectious or inflammatory disease or recent surgery; affected by malabsorption, such as sprue and Crohn's disease; affected by hypothyroidism or hyperthyroidism; having gallstones and biliary tract obstruction; having a weight loss diet at the time of the study; pregnancy or lactation; history of allergy to artichoke family plants and their products; menopause

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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, Golgasht Street

City

Tabriz

Postal code

Approval date

2014-11-15, 1393/08/24

Ethics committee reference number

93120

Health conditions studied

1

Description of health condition studied

metabolic syndrom

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Fasting blood suger and Serum Lipid profile

Timepoint

at the beginning and end of intervention

Method of measurement

Fasting blood suger by enzymatic method and triglycerid, total cholestrol and HDL-C by espectrophotometry method and LDL-C by Friedewald Formula

2

Description

Serum levels of total antioxidants capacity and Malondialdehyde

Timepoint

at the beginning and end of intervention

Method of measurement

TAC: Espectrophotometry by Rabdox enzymatic kit; MDA: Reaction with thiobarbituric acid by fluorimetry method

3

Description

Serum level of CETP

Timepoint

at the beginning and end of intervention

Method of measurement

By Laboratory ELISA Kits

Secondary outcomes

1

Description
Energy and nutrient intake
Timepoint
3 times; at first, midst and the end of intervention
Method of measurement
3 dayes food record was used and analyzed with Nutritionist 4 software

2

Description
Serum level of Insulin
Timepoint
at the beginning and end of intervention
Method of measurement
Chemilumines

3

Description
Physical activity level
Timepoint
3 times; at first, midst and the end of intervention
Method of measurement
International questionnaire

4

Description
Systolic and Diastolic blood pressure
Timepoint
at the beginning and end of iintervention
Method of measurement
Automatic Blood Pressure Monitoring

5

Description
Anthropometric measurements
Timepoint
3 times during the study: at the beginning, midst and end of intervention
Method of measurement
Anthropometric measurements including weight using calibrated Omron scale with a precision of 0.1 kg and a minimum of clothes, height, waist and hip circumference using a tape measure with an accuracy of 0.1 cm will be done, and BMI will be calculated.

6

Description
Body composition
Timepoint
3 times during the study: at the beginning, midst and end of intervention
Method of measurement
Measurement of body composition using Omron Bioelectric Impedance Analyzer.

Intervention groups

1

Description
intervention group: 1800 mg hydro-alcoholic artichoke leaf extract as 4 tablets per day for 3 months
Category
Treatment - Other

2

Description
Control group: 1800 mg placebo containing corn starch, lactose and Avicel as 4 tablets per day for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khoy City
Full name of responsible person
khatereh Rezazadeh
Street address
City
Khoy

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences
Full name of responsible person
Mohammad - Reza Rashidi
Street address
Tabriz University of Medical Sciences
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 (VCR) of 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

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Fax
Email
Web page address

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