

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

+98 41 1335 1113

Email address

ebrahimimamagani@tbzmed.ac.ir

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 Rabdiox 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 days 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 intervention

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

Contact

Name of organization / entity

Ph.D Student of Nutrition

Full name of responsible person

khatereh Rezazadeh

Position

Faculty of Nutrition, Tabriz University Of Medical Sciences

Other areas of specialty/work

Street address

Faculty of Nutrition, Attar Neyshaboori Avenue, Golgasht Street

City

Tabriz

Postal code

Phone

+98 41 3335 2292

Fax

Email

rezazadekhatereh@gmail.com

Web page address

+98 41 3335 2295

Fax

Email

ebrahimimamagani@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

khatereh Rezazadeh

Position

Ph.D Student of Nutrition

Other areas of specialty/work

Street address

Faculty of Nutrition, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Phone

00

Fax

Email

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehranghiz Ebrahimi Mamaghani

Position

Associate Professor

Other areas of specialty/work

Street address

Faculty of Nutrition, Golgasht Street, Attar neishaboori Avenue

City

Tabriz

Postal code

Phone

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