

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

the effect of green coffee extract supplementation on serum level of chemerin, malondialdehyde, nutritional status and metabolic status in people with metabolic syndrom

Protocol summary

Summary

The purpose of this clinical trial is to evaluate the effect of green coffee extract supplementation on serum level of chemerin, malondialdehyde, nutritional status and metabolic status in patients with metabolic syndrome. Sample size is 44 person. This trial is a randomized, double-blind, placebo-controlled clinical trial. Blinding will be performed for patients and the study researchers. Subjects were randomly divided into intervention and control groups. Randomization is based on a random-number table. After meeting the inclusion and exclusion criteria, patients will allocated randomly (by random numbers table) into two intervention and control groups. At the beginning of the study, five ml of blood (after 8-12 hours of fasting) will be taken. After determining the persons to the intervention and control groups, a cloudy and closed envelopes will be used for allocation to two groups. For everyone in the envelopes, the capsule will be similar. The subjects will take two capsules (400 mg) daily with breakfast and lunch. Fasting blood was used for serum level of chemerin, lipid Parameters profile, fasting blood glucose, insulin, HbA1c and malondialdehyde. Blood pressure also was measured. The General Information Questionnaire, Anthropometric indices, physical activity questionnaire and appetite level questionnaire and 24-hour recall will be filled out in at the start of the intervention, the fourth week (for follow up) and the eighth week by the participants. They will be evaluated based on the following criteria: persons 50-25 years of age and with metabolic syndrome Exclusion criteria: the use of lipid lowering agents; weight loss medicines; the use of fasting blood glucose lowering agents; the use of antihypertension agents and addiction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081635736N1**
Registration date: **2017-08-22, 1396/05/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-22, 1396/05/31

Registrant information

Name

mehdi fasihi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 4653 0325

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fasihim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of green coffee extract supplementation on serum level of chemerin, malondialdehyde, nutritional status and metabolic status in people with metabolic syndrom

Public title

the effect of green coffee on metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: people with metabolic syndrome; 25-50 year old person; willingness to cooperate. Exclusion criteria: use of lipid or glucose or blood pressure lowering agents; use of body weight loss medications; Addiction and Smoking; Menopause; Sensitivity to placebo; cancer; cardiovascular disease; liver disorders; kidney disease and anemia; use of antioxidant supplements, fish oil supplements and alcohol; pregnancy and lactation

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Ghol-Ghasht Ave, Azadi St, Tabriz

City

Tabriz

Postal code

Approval date

2016-09-26, 1395/07/05

Ethics committee reference number

IR.TBZMED.REC.1395.669

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E66.0,E11.

ICD-10 code description

Obesity due to excess calories, Non-insulin-dependent diabetes mellitus with unspecified complications,Secondary hypertension, unspecified

Primary outcomes

1

Description

Serum Chemerin

Timepoint

At baseline and after 2 month of intervention

Method of measurement

ELISA

2

Description

Malondialdehyde

Timepoint

At baseline and after 2 month of intervention

Method of measurement

Spectrophotometry of Thiobarbituric Acid

Secondary outcomes

1

Description

whight

Timepoint

At baseine and 4th and 8th weeks

Method of measurement

scale

2

Description

BMI

Timepoint

At baseine and 4th and 8th weeks

Method of measurement

W/H.t2

3

Description

Waist circumference

Timepoint

At baseine and 4th and 8th weeks

Method of measurement

Standard plastic tape

4**Description**

Hip circumference

Timepoint

At baseline and 4th and 8th weeks

Method of measurement

Standard plastic tape

5**Description**

Waist/Hip ratio

Timepoint

At baseline and 4th and 8th weeks

Method of measurement

Waist / Hip

6**Description**

blood pressure

Timepoint

At baseline and 4th and 8th weeks

Method of measurement

Standard mercury manometer

7**Description**

Physical activity

Timepoint

At baseline and 4th and 8th weeks

Method of measurement

The International physical activity questionnaire

8**Description**

Triglyceride

Timepoint

Beginning of the study and after two months

Method of measurement

Enzymatic and colorimetric method

9**Description**

Total Cholesterol

Timepoint

Beginning of the study and after two months

Method of measurement

Enzymatic and colorimetric method

10**Description**

LDL-C

Timepoint

Beginning of the study and after two months

Method of measurement

Enzymatic and colorimetric method

11**Description**

HDL-C

Timepoint

Beginning of the study and after two months

Method of measurement

Enzymatic and colorimetric method

12**Description**

Fasting blood glucose

Timepoint

Beginning of the study and after two months

Method of measurement

Glucose oxidase enzymatic and colorimetric

13**Description**

Insulin level

Timepoint

Beginning of the study and after two months

Method of measurement

Enzymatically using autoanalyzer

14**Description**

Insulin resistance

Timepoint

Beginning of the study and after two months

Method of measurement

HOMAIR

15**Description**

HbA1c

Timepoint

Beginning of the study and after two months

Method of measurement

Colorimetric - Ion Spectrophotometer

16**Description**

Nutritional status

Timepoint

At baseline and 4th and 8th weeks

Method of measurement

The questionnaires and Software nutrition 4

Intervention groups**1****Description**

Intervention group: patients will receive a daily two capsules containing 400 mg of green coffee extract, for

two months. Capsules should taken 30 minutes before breakfast and lunch with glass of water.

Category

Treatment - Drugs

2**Description**

control group: patients will receive a daily two placebo capsules , for two months. Capsules should taken 30 minutes before breakfast and lunch with a glass of water.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of nutrition Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali barzegar

Street address

East Azarbaijan, Tabriz, Golghast St, Tabriz University of Medical Sciences, Faculty of Nutrition and Health

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

Dr. Mohammad Reza Rashidi, Research Assistant of Tabriz University of Medical Sciences

Street address

Ghol-Ghasht Ave.,Azadi St.,Tabriz.

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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**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Fasihi

Position

MSc. Student of Nutrition

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Full name of responsible person

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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