

# 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)

##### Phone

+98 31 4653 0325

##### Email address

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.

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Fasihi

**Position**

MSc. Student of Nutrition

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00

**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*