

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of lutein supplementation on anthropometric parameters, metabolic and inflammatory status, sirtuin1 and plasminogen activator inhibitor-1 in obese individuals on a low-calorie diet

#### Protocol summary

##### Study aim

The aim of the present study is to investigate the effect of lutein supplementation on anthropometric parameters, metabolic and inflammatory status, sirtuin1 and plasminogen activator inhibitor-1 in obese individuals on a low-calorie diet

##### Design

Randomized double blind clinical trial with two arm parallel groups

##### Settings and conduct

Volunteers under an nutritionist with diagnosis of obesity will be randomly assigned to one of the two supplement or placebo groups. The duration of the study will be 12 weeks. The boxes containing lutein and placebo capsules will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of supplement each group receives.

##### Participants/Inclusion and exclusion criteria

46 individuals with obesity (BMI of 25-35 kg / m<sup>2</sup>) will be included in the study. Pregnancy, lactation, taking anti-diabetic drugs, anti-inflammatory drugs, statines and developing cardiovascular, renal and hepatic diseases, and cancer are among the exclusion criteria

##### Intervention groups

Individuals in the lutein group will use a 500 milligrams capsule with 20 milligrams lutein with lunch, daily. In the placebo group, the capsule will contain 500 milligrams of maltodextrin.

##### Main outcome variables

Nutritional status (anthropometric indices, and calorie and macronutrients intake), metabolic status (fasting blood glucose, insulin, Insulin resistance index (HOMA-IR) and lipid profiles (TC, TG, HDL-c LDL-c), inflammatory status (hs-CRP and IL-6), serum levels of free fatty acids, nitric oxide, endothelin-1, plasminogen activator inhibitor-1, and Sirtuin1.

#### General information

##### Reason for update

Addition of leptin, adiponectin, and oxidative stress to the primary outcomes of the study

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191109045382N1**

Registration date: **2019-12-07, 1398/09/16**

Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **1**

##### Registration date

2019-12-07, 1398/09/16

##### Registrant information

##### Name

Zohreh Ghoreishi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 1712

##### Email address

ghoreyshiz@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-10, 1398/10/20

##### Expected recruitment end date

2020-05-19, 1399/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of lutein supplementation on anthropometric parameters, metabolic and inflammatory status, sirtuin1 and plasminogen activator inhibitor-1 in obese individuals on a low-calorie diet

**Public title**

The effect of lutein on cardiovascular risk factors

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

46 individuals with obesity (BMI of 30-40 kg / m<sup>2</sup>)

Pregnancy, lactation

**Exclusion criteria:**

taking anti-diabetic drugs, statines, or anti-inflammatory drugs developing cardiovascular, renal and hepatic diseases, cancer. bariatrics surgeries

**Age**

From **45 years** old to **64 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

46 eligible participants will be randomly allocated to intervention and placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the main investigators (including the student and her supervisors and adviser professors), as well as the patients will be blinded to the type of the supplement (lutein or placebo) received by each group. The person responsible for preparing the supplement sachets (who is completely unrelated to the study) will be asked to assign a three-digit code to each of the two capsules (lutein and placebo) and keep the codes for himself until the end of the study and data analysis.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Research Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Attar Neishabouri Ave., Golgasht St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166/1573113

**Approval date**

2019-10-15, 1398/07/23

**Ethics committee reference number**

IR.TBZMED.REC.1398.692

**Health conditions studied****1****Description of health condition studied**

Cardiovascular diseases, obesity

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Anthropometric Indices

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Measurement of height and weight without shoes and with minimum clothes on, by Seca stadiometer and scale, respectively. Measurement of waist and hip circumference by a tape measure and body mass index (BMI) by dividing weight (kg) by height squared (m<sup>2</sup>)

**2****Description**

Calorie and macronutrients intake

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

The intake of calorie and macronutrients from the diet of the subjects with using a 3 day food record questionnaire and analysis by the nutritionist 4 program.

### 3

**Description**

Fasting blood sugar

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Enzymatic method

### 4

**Description**

Insulin

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

ELISA

### 5

**Description**

Lipid profile

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Measurement of total cholesterol, HDL- cholesterol and triglyceride through enzymatic methods and calculation of LDL- cholesterol by Friedewald equation

### 6

**Description**

Insulin resistance

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Insulin resistance with HOMA-IR and calculation by this equation :  $[\text{fasting insulin (mU / ml)} \times \text{fasting glucose (mg / dl)}] / 405$

### 7

**Description**

Inflammatory indices

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Measurement of serum hs-CRP by immunoturbidometry method and serum IL-6 by ELISA

### 8

**Description**

Free fatty acids

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Chloromerer kit

### 9

**Description**

plasminogen activator inhibitor-1

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

ELISA

### 10

**Description**

Sirtuin1

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

ELISA

### 11

**Description**

Endothelin-1

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

ELISA

### 12

**Description**

Nitric oxide

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Chloromerer kit

### 13

**Description**

Adiponectin

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

ELISA

### 14

**Description**

leptin

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

ELISA

### 15

**Description**

Oxidative stress

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

Prooxidant Antioxidant Balance (PAB)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Patients in this group will receive lutein supplement for 12 weeks. The supplement is a capsule containing 20 milligrams of lutein (a product by Bulk Supplements Co. and made in the United States) which will be used once a day with lunch.

### Category

Prevention

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Nutrition clinic

#### Full name of responsible person

Fatemeh Hajizadeh-Sharafabad

#### Street address

Azadi street, Sheikholraees

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5163639888

#### Phone

+98 44 3234 3476

#### Email

hajizadehfa@tbzmed.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Alireza Ostad Rahimi

#### Street address

Faculty of Nutrition and Food Sciences

#### City

Tabriz

#### Province

East Azarbaijan

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5166614711

#### Phone

+98 41 3335 2292

#### Email

nut-rc@tbzmed.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Tabriz University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr. Zohreh Ghoreyshi

#### Position

Associate Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

#### Street address

Faculty of Nutrition and Food Sciences., Attar  
Neishabouri St., Golghast St

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#### Phone

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#### Email

ghoreyshiz@tbzmed.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr Ali Tarighat-Esfanjeni

#### Position

Associate Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

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tarighata@tbzmed.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fatemeh Hajizadeh-Sharafabad

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

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+98 44 3234 3476

**Email**

hajizadehfa@tbzmed.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Data collected for the primary outcomes will be shared.

**When the data will become available and for how long**

Access starting 12 months after publication

**To whom data/document is available**

The data will only be available for people working in academic institutions.

**Under which criteria data/document could be used**

The data of the present study will only be accessible by other researchers, for conducting meta-analysis.

**From where data/document is obtainable**

Ms. Fatemeh Hajizadeh-Sharafabad, E-mail address:  
fm.hajizadeh@gmail.com, cellphone number: 0098  
9141894602

**What processes are involved for a request to access data/document**

The applicant should provide a brief description of the aims and methods of his his Meta-analysis. His request will be assessed and, if agreed, the data will be emailed to the applicant. All these procedures will take no longer than 20 days.

**Comments**