

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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 / m²) 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 / m2)

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

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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 (m2)

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

ELIZA

14

Description

leptin

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELIZA

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostad Rahimi

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ali Tarighat-Esfanjani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

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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