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 / 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
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 (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 : [fasting insulin (mU / ml) × 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
Street address
Azadi street, Sheikholraees
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Phone
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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
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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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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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