

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of ellagic acid supplementation on glycemic status, lipid profile, oxidative stress indices and anthropometric parameters in the military with type 2 diabetes

Protocol summary

Study aim

The effect of ellagic acid supplementation on metabolic and anthropometric status in the military with diabetes type II

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. RAS software was used for randomization.

Settings and conduct

Eligible individuals referring to Shahid Mahallati Hospital in Tabriz will enter the study after obtaining written consent. Patients will be randomly divided into two groups including 1. The group receiving ellagic acid supplement 2. The group receiving placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria Willingness to cooperate Diabetes type 2 Age 60-30 years Patients whose blood sugar is well controlled by taking oral hypoglycemic drugs. Body Mass Index (BMI): 23-35 kg / m² Both sexes Exclusion criteria Reluctance to cooperate Taking multivitamin and mineral supplements during the last 3 months Follow a specific diet and physical activity for the past 3 months Taking corticosteroids and nonsteroidal anti-inflammatory drugs Insulin users Chronic diseases such as cardiovascular, renal, hepatic and hypothyroidism and hyperthyroidism. Having specific physiological conditions such as pregnancy and lactation

Intervention groups

Intervention group: Patients in this group will receive 1capsules of 250 milligrams of ellagic acid (product by Exir Gostar Espadana Co. and made in The Iran) for 8 weeks a day. Control group: Control group: Patients in this group will receive Microcrystalline cellulose capsules for 8 weeks which are same size and shape (product by Exir Gostar Espadana Co. and made in The Iran) and used once a day with lunch.

Main outcome variables

glycemic status, lipid profile, oxidative stress indices and anthropometric parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210219050412N1**

Registration date: **2021-04-15, 1400/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

Registration date

2021-04-15, 1400/01/26

Registrant information

Name

Vahid Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 1026

Email address

malekivahid433@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of ellagic acid supplementation on glycemic status, lipid profile, oxidative stress indices and anthropometric parameters in the military with type 2 diabetes

Public title
Ellagic acid and type 2 diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate Diabetes type 2 Age 60-30 years Patients whose blood sugar is well controlled by taking oral hypoglycemic drugs. Body Mass Index (BMI): 23-35 kg / m² Both sexes
Exclusion criteria:
Reluctance to cooperate Taking multivitamin and mineral supplements during the last 3 months Follow a specific diet and physical activity for the past 3 months Taking corticosteroids and nonsteroidal anti-inflammatory drugs Insulin users Chronic diseases such as cardiovascular, renal, hepatic and hypothyroidism and hyperthyroidism. Having specific physiological conditions such as pregnancy and lactation

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by block method with a block size of 4. For each of the 6 possible cases for the quadruple block, the numbers are assigned as follows AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), BAAB (6) With the help of a table of random numbers, the numbers between 1 and 6 are selected and the treatment allocation list is determined according to each number. To execute the generated random sequence, the method of hiding coded boxes or cans is used. In this method, the cans are numbered in a random sequence and inside the boxes, the desired intervention (drug) or a sheet on which the random allocation is written, is provided to the executor with the condition that the boxes are completely sealed and The researcher assigns patients to the standard intervention and treatment group based on the order of patients' admission. Tools: Create random sequences of 4 random blocks Concealment to execute random sequences on study participants will be

done. How to make blocks: Randomly select the block and read the letters from right to left. Hiding will be done by the method of cans that are numbered in random sequence. The cans are the same weight and shape and will be prepared by an independent researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, no patient and investigator will be aware of the treatment assignments for the duration of the study. For blinding the trial, the Ellagic acid capsules and placebo, will be identical in appearance, packaging, and labeling. All capsules will be packed and encoded by the company.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, MollaSadra street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1484958693

Approval date

2021-01-09, 1399/10/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.048

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes

Primary outcomes

1

Description

Level of fasting blood sugar (FBS)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of fasting blood sugar (FBS) by enzymatic method

2

Description

Level of insulin

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of insulin by enzymatic method

3

Description

Level of hemoglobin A1C

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of hemoglobin A1C by enzymatic method

4

Description

HOMA-IR scores

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of HOMA-IR score using formula.

5

Description

Serum level of total cholesterol (TC)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of total cholesterol (TC) level via enzymatic kit

6

Description

Serum level of triglyceride

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of triglyceride (TG) level via enzymatic kit

7

Description

Serum level of HDL

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of HDL level via enzymatic kit

8

Description

Serum level of LDL

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of LDL using friedewald equation

9

Description

Serum level of total antioxidant capacity (TAC)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of total antioxidant capacity (TAC) by spectrophotometry

10

Description

Assessment of the body composition

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Assess body composition using the body composition analyzer

11

Description

Serum level of malondialdehyde (MDA)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of malondialdehyde (MDA) by spectrophotometry

Secondary outcomes

1

Description

Physical activity level

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Via IPAQ questionnaire

2

Description

Assessment of dietary intake

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

3-day food record

Intervention groups

1

Description

Intervention group: Patients in this group will receive 1 capsules of 250 milligrams of ellagic acid (product by Exir Gostar Espadana Co. and made in The Iran) for 8 weeks a day.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive Microcrystalline cellulose capsules for 8 weeks which are same size and shape (product by Exir Gostar Espadana Co. and made in The Iran) and used once a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mahallati Hospital

Full name of responsible person

Vahid Maleki

Street address

Shahid Mahallati Hospital, Railway Street

City

Tabriz

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2

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Maryam Taghdir

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Vahid Maleki

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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