

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment the ellagic acid supplementation effect on glycemic status, insulin resistance, inflammatory factors, antioxidant status and expression of miR146-a in patients with type 2 diabetes: double blind randomized clinical trial

Protocol summary

Study aim

Improving glycemic status, insulin resistance, antioxidant status and inflammatory factors in patients with type 2 diabetes

Design

In this study, 44 patients with type 2 diabetes who are eligible for inclusion in the study and referred to the Department of Endocrinology and Metabolism of Velayat Hospital of Qazvin University of Medical Sciences are selected. Participants are randomly assigned to two intervention and control groups and each participant is assigned a code.

Settings and conduct

This study will be done by referring to the Specialty Hospital of Qazvin University of Medical Sciences. The intervention and control group will receive 200 mg of ellagic acid or placebo daily for 2 months, respectively. Each person will complete questionnaires of consent, individual, physical activity, and 24-hour recall. Fasting blood samples were also collected at the beginning and end of the study in 10 ml from participants. In this study, participants will be randomly divided into two groups (22 persons) through the table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to work, type 2 diabetes, age 25- 55, non-modification of treatment and medications for at least the past 2 months, moderate physical activity Exclusion criteria: Use of insulin, diabetes for more than 10 years, pregnancy and lactation, patients with severe renal and hepatic dysfunction, alcohol consumption

Intervention groups

Intervention group: the group receiving ellagic acid (200mg daily) Control group: placebo group

Main outcome variables

Fasting blood sugar, 2 hours sugar, Glycosylated

hemoglobin, insulin resistance, lipid profile, oxidative stress indices, inflammatory factors, expression of miR146-a, SIRT1, and Fetuin A

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N13**

Registration date: **2019-09-24, 1398/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-11, 1398/07/19**

Update count: **1**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

Email address

khadem.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-31, 1398/06/09

Expected recruitment end date

2019-11-30, 1398/09/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment the ellagic acid supplementation effect on glycemic status, insulin resistance, inflammatory factors, antioxidant status and expression of miR146-a in patients with type 2 diabetes: double blind randomized clinical trial

Public title
Ellagic acid supplementation effect in patients with type 2 diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women with with type 2 diabetes Willingness to work Age 25- 55 Non-modification of treatment and medications for at least the past 2 months Moderate physical activity

Exclusion criteria:

Insulin using Having diabetes for more than ten years Pregnancy and breastfeeding Patients with severe renal and hepatic dysfunction, Alcohol consumption

Age
From **24 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
It will be done randomly using lottery method. Each patient will receive a number or code, and then we will write the numbers on pieces of paper. We will then place the pieces of paper in a container and select the samples according to the sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Supplements and placebo will be placed in similar containers and encode by someone except investigator, so patients and the investigator will be blinded to medicine and placebo groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University Of Medical Sciences

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2019-07-19, 1398/04/28

Ethics committee reference number

IR.QUMS.REC.1398.079

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

2

Description

2 hours sugar

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

3

Description

Insulin resistance

Timepoint

Before the intervention and after the intervention
Method of measurement
Using the formula

4

Description
Glycosylated hemoglobin
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

5

Description
Lipid profile
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

6

Description
Total antioxidant capacity
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

7

Description
Glutathione peroxidase enzyme
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

8

Description
Superoxide dismutase enzyme
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

9

Description
Malondialdehyde
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

10

Description
Inflammatory factors
Timepoint
Before the intervention and after the intervention

Method of measurement
Eliza

11

Description
Expression of miR146-a
Timepoint
Before the intervention and after the intervention
Method of measurement
Real-Time PCR

12

Description
SIRT1
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

13

Description
Fetuin A
Timepoint
Before the intervention and after the intervention
Method of measurement
Eliza

14

Description
Sleep quality
Timepoint
Before intervention and after intervention
Method of measurement
Petersburg's sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ellagic acid, a capsule 200 mg per daily for two months, Manufacturer: Supplement Spot
Category
Treatment - Drugs

2

Description
Control group: A daily placebo capsule containing wheat flour for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Hossein Khadem Haghighian

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Peimani

Street address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice-Chancellor for Research of Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Hossein Khadem Haghighian

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data after people are unrecognizable

When the data will become available and for how long

After completing the study and analyzing the data

To whom data/document is available

All researchers

Under which criteria data/document could be used

There is no objection to the use of data provided the source of the resource.

From where data/document is obtainable

By contacting the email address of a person responsible for general inquiries khademnut@yahoo.com

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

Six months after the study

Comments