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

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Phone
+98 28 3333 6001

Email
khademnut@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Peimani

Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Phone
+98 28 3333 6001

Email
khademnut@yahoo.com

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

Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Phone
+98 28 3333 6001

Email
khademnut@yahoo.com

Person responsible for scientific 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

Street address
Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City
Qazvin

Province
Qazvin

Postal code
59811 -34197

Phone
+98 28 3333 6001

Email
khademnut@yahoo.com

Person responsible for updating data

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

Street address

Qazvin University of Medical Science, Shahid Bahonar Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

khademnut@yahoo.com

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