

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Assessment of the Ellagic acid supplementation effect on lipid profile, liver enzymes, oxidative stress status and inflammatory factors in patients with non-alcoholic fatty liver disease: double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Determination of ellagic acid supplement effect in patients with non-alcoholic fatty liver disease

##### Design

In this study, 44 patients with non-alcoholic fatty liver disease who are eligible to enter the study are selected. Participants are randomly divided into intervention and control groups and each participant will be assigned a code.

##### Settings and conduct

The aim of this study is to evaluate the ellagic acid supplement as a randomized, double-blind clinical trial on patients with non-alcoholic fatty liver disease referring to the specialized department of the hospital of Qazvin University of Medical Sciences. People with non-alcoholic fatty liver disease after the introduction by a specialist, counselor for this project, will be randomly divided into two groups of intervention and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-55 years old patient with non-alcoholic fatty liver, confirmation of non-alcoholic fatty liver with liver ultrasound, having a body mass index less than 30, consent signed by the patient. Exclusion criteria: pregnancy, lactation, infectious disease, inflammatory disease, Cushing's syndrome, adrenal gland tumor, hypothyroidism, diabetes, and cancer, taking antioxidant supplements in the last three months, taking medication in the last three months including glucocorticoids drugs, lipid-lowering drugs, and weight-loss drugs.

##### Intervention groups

Intervention group: the group receiving ellagic acid (180 mg daily) Control group: placebo group

##### Main outcome variables

Fasting blood sugar, insulin resistance, lipid profile, liver enzymes, oxidative stress indices, inflammatory factors

and adiponectin hormone

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141025019669N21**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

##### Registration date

2022-01-23, 1400/11/03

##### Registrant information

##### Name

Hossein Khadem Haghghian

##### 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

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-04-20, 1401/01/31

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Assessment of the Ellagic acid supplementation effect on lipid profile, liver enzymes, oxidative stress status and inflammatory factors in patients with non-alcoholic fatty liver disease: double-blind randomized clinical trial

**Public title**  
Ellagic acid supplementation in patients with non-alcoholic fatty liver disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

18-55 years old patient with non-alcoholic fatty liver, confirmation of non-alcoholic fatty liver with liver ultrasound Having a body mass index of less than 30 A consent signed by the patient.

**Exclusion criteria:**

Pregnancy and lactation Infectious disease, inflammatory disease, Cushing's syndrome, adrenal gland tumor, hypothyroidism, diabetes, and cancer. Taking antioxidant supplements in the last three months Taking medication in the last three months including glucocorticoids drugs, lipid-lowering drugs, and weight-loss drugs.

**Age**  
From **18 years** old to **55 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **44**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
It will be done randomly using the 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 encoded by someone except the 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**

2021-12-13, 1400/09/22

**Ethics committee reference number**

IR.QUMS.REC.1400.362

**Health conditions studied**

**1**

**Description of health condition studied**

Non alcoholic fatty liver disease

**ICD-10 code**

K75.8

**ICD-10 code description**

Other specified inflammatory liver diseases

**Primary outcomes**

**1**

**Description**

Fasting blood sugar

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**2**

**Description**

Insulin

**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**

Total antioxidant capacity

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**5**

**Description**

Malondialdehyde

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**6**

**Description**

Lipid profile

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**7**

**Description**

Liver enzymes

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**8**

**Description**

Inflammatory factors

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**9**

**Description**

Adiponectin hormone

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Eliza

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Ellagic acid, a capsule 180 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 Haghghian

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**Email**

khademnut@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Mirhashemi

**Street address**

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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**

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 scientific inquiries

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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 publishing the article

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

There is nothing wrong with using the data as long as the source of the data is mentioned.

**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**

After consulting with the research team, the data will be provided to the applicant, which will probably be a one-month process.

**Comments**