

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the Effect of Ellagic Acid Supplementation on Antioxidant Status in Patients with Major Depressive Disorder: A randomized, double-blind clinical trial

Protocol summary

Study aim

Improving depression status, and antioxidant status in patients with major depressive

Design

In this clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, 60 patients with major depression who meet the inclusion criteria and are referred to Shahid Zare Hospital of Mazandaran University of Medical Sciences are selected. Participants are randomly divided into intervention and control groups using random blocks and a code is assigned to each participant.

Settings and conduct

This study will be done by referring to the Specialty Shahid Zare Hospital of Mazandaran 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 a consent form, a personal information questionnaire, 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 (30 persons) through the table of random numbers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to work, major depressive, age 18- 55, non-modification of treatment and medications for at least the past 2 months Exclusion Criteria: 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

Depression score, oxidative stress indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N15**

Registration date: **2021-02-26, 1399/12/08**

Registration timing: **prospective**

Last update: **2021-02-26, 1399/12/08**

Update count: **0**

Registration date

2021-02-26, 1399/12/08

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

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-26, 1400/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of Ellagic Acid Supplementation on Antioxidant Status in Patients with Major Depressive Disorder: A randomized, double-blind clinical trial

Public title

Ellagic acid supplementation effect in patients with Major Depressive

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women with Major Depressive Willingness to work Age 18- 55 Non-modification of treatment and medications for at least the past 2 months

Exclusion criteria:

Pregnancy and breastfeeding Patients with severe renal and hepatic dysfunction Alcohol consumption

Age

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

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 Mazandaran University Of Medical Sciences

Street address

Vice chancellor for research, Moallem Square, Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.MAZUMS.REC.1399.697

Health conditions studied

1

Description of health condition studied

Major depressive episode

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Severity of depression

Timepoint

Before the intervention and after the intervention

Method of measurement

Hamilton Rating Scale

Secondary outcomes

1

Description

Total antioxidant capacity

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

2

Description

Malondialdehyde

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

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

Shahid Zare hospital

Full name of responsible person

Gholamreza Houshmand

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No 8, Zabihi buildig, Niloufar Alley, Farah Abad blvd, Khazar Square, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

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majsaeedi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Gholamreza Houshmand

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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 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

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

Comments