Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3375 2135

Email address

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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
Street address
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
Street address
Moallem Square
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48175861
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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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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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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Email

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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