

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of oral gallic acid supplementation on antioxidant status in people with major depression

Protocol summary

Study aim

Improvement in depression and antioxidant status in patients with major depression

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 Gallic acid or placebo daily for 2 months, respectively. Each person will complete a consent form, a personal information questionnaire, physical activity, and 24-hour diet 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 cooperate, major depressive, age 18- 55, no change in treatment and medications in the last 2 months Exclusion Criteria: pregnancy and lactation, patients with severe renal and hepatic impairment, alcohol consumption

Intervention groups

Intervention group: the group receiving Gallic 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: **IRCT20141025019669N17**
Registration date: **2021-03-22, 1400/01/02**
Registration timing: **prospective**

Last update: **2021-03-22, 1400/01/02**

Update count: **0**

Registration date

2021-03-22, 1400/01/02

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

The effect of oral gallic acid supplementation on antioxidant status in people with major depression

Public title

The effect of gallic acid supplementation in patients with major depression

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

Participants will be allocated to trial groups (intervention and placebo groups) randomly using Random Allocation Software (RAS) through random block sizes of 4 and 6 with an allocation ratio of 1:1. Patients will receive a sealed container of supplements. Random sequencing allocation will be produced by the person who has not participate in the research. Containers will be numbered from 1 to 60 according to the sequence generated.

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplements and placebo will be placed in similar containers and will be coded by someone other than the researcher, 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

2020-09-16, 1399/06/26

Ethics committee reference number

IR.MAZUMS.REC.1399.644

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: Gallic 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

City

Sari

Province

Mazandaran

Postal code

481751665

Phone

+98 11 3354 3081

Email

g.houshmand@mazums.ac.ir

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

City

Sari

Province

Mazandaran

Postal code

48175861

Phone

+98 11 3354 3082

Email

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

Street address

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

City

Sari

Province

Mazandaran

Postal code

481751665

Phone

+98 11 3354 3081

Email

g.houshmand@mazums.ac.ir

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

Mazandaran University of Medical Sciences

Full name of responsible person

Gholamreza Houshmand

Position

Faculty member

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Ph.D.

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Street address

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

City

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Province

Mazandaran

Postal code

481751665

Phone

+98 11 3354 3081

Email

g.houshmand@mazums.ac.ir

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 publishing the article

Comments