

# 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

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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Khazar Square, Sari

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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 publishing the article

**Comments**