

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of the effect of clove-based Iranian traditional medicine (*Eugenia Caryophyllata*) On improving the score of Hamilton questionnaire in patients with depression

#### Protocol summary

##### Study aim

Determining and comparing level of depression in patients receiving traditional Iranian medicine based on cloves and placebo 2, 4 and 6 weeks after treatment

##### Design

A clinical trial with a control group, with parallel groups, double-blind, phase 2-3, was performed on 62 patients, randomized with random number generator software.

##### Settings and conduct

This study was performed on patients referred to 505 AJA (The Islamic Republic of Iran Army) Psychiatric Hospital who were diagnosed with major depression by psychiatrists based on DSM-5 (Diagnostic and Statistical Manual of Mental Disorders). In addition to the main treatment with citalopram, patients were given medication or placebo and the patient's depression status was assessed at 2, 4 and 6 weeks after starting treatment. The patient and the researcher were blinded to the intervention group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: A score of 19 or higher on the 17-item HAM-D (hamilton depression scale) scoring tool and a score of 2 or higher on the first HAM-D item No entry conditions: Received any type of antidepressant in the past months Received an electric shock during the last 2 months Have evidence in favor of psychosis or other mental illness Suicidal thoughts (score higher than 2 on HAM-D suicide item) Addiction or abuse of alcohol or other substances (excluding nicotine) Uncontrollable physical diseases such as thyroid, heart and liver diseases

##### Intervention groups

All patients will be treated with citalopram 10 mg daily for two weeks and then 20 mg daily. Participants are randomly divided into two groups; The first group is given the product of traditional Iranian medicine based on cloves at a dose of 250 mg per day and the second

group is given a placebo for six weeks.

##### Main outcome variables

Hamilton Depression Inventory; Side effects of the drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220426054668N1**

Registration date: **2022-06-21, 1401/03/31**

Registration timing: **retrospective**

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

##### Registration date

2022-06-21, 1401/03/31

##### Registrant information

##### Name

Mohammadreza Ghasemzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2248 1806

##### Email address

m.rezaghasemzadeh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-30, 1400/04/09

##### Expected recruitment end date

2022-02-09, 1400/11/20

##### Actual recruitment start date

2021-06-30, 1400/04/09

**Actual recruitment end date**

2022-03-09, 1400/12/18

**Trial completion date**

2022-04-20, 1401/01/31

**Scientific title**

Evaluation of the effect of clove-based Iranian traditional medicine (*Eugenia Caryophyllata*) On improving the score of Hamilton questionnaire in patients with depression

**Public title**

Evaluation of the effect of cloves in the treatment of depression

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

A score of 19 or higher on the 17-item HAM-D Scoring Tool and a score of 2 or higher on the first HAM-D item

**Exclusion criteria:**

Received any type of antidepressant in the past months  
Received electroshock during the last 2 months  
Having evidence in favor of psychosis or other mental illnesses  
Suicidal thoughts (score higher than 2 on HAM-D suicide item)  
Addiction or abuse of alcohol or other substances (excluding nicotine)  
Uncontrollable physical diseases such as thyroid, heart and liver diseases  
Patient dissatisfaction with participation in the study

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **62**

Actual sample size reached: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible patients are included in the study and are divided into two groups A and B by sequentially numbered method. Randomization is done by random number generator software in quadruple blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants and the physician are both blinded to the treatment received. After obtaining patient information, the researcher gives the patient a sealed envelope that contains code A (a product of traditional medicine based on cloves) or code B (placebo). Without opening the envelope, the patient presents it to the pharmacist's colleague, so that after the relevant code is determined, the drug A or B, which are covered by the manufacturer,

will be given to the patient. The pharmacist colleague records the patient's name and code without identifying the medication, and this information will be kept until the end of the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of AJA University of Medical Sciences

**Street address**

AJA University of Medical Sciences, Shaheed Etemadzadeh St, West Fatemi Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1411718541

**Approval date**

2021-07-03, 1400/04/12

**Ethics committee reference number**

IR.AJAUMS.REC.1400.084

**Health conditions studied****1****Description of health condition studied**

Major depressive disorder

**ICD-10 code**

F32

**ICD-10 code description**

Major depressive disorder, single episode

**Primary outcomes****1****Description**

Depression score on the Hamilton questionnaire

**Timepoint**

Before the study, two, four and six weeks after starting treatment

**Method of measurement**

Hamilton Depression Inventory

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: Processed clove syrup; One gram of cloves with ten grams of pomegranate juice and one gram of honey are kept in an incubator at 40 ° C for one week. Then the desired syrup is prepared by adding sugar. The product will be stored in a sterile glass container and closed until dark, in the dark and in the refrigerator at 4 ° C. At a dose of 250 mg (3 cc) daily for 6 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: placebo; Ten grams of pomegranate juice and one gram of honey are stored in an incubator at 40 degrees for one week. Then the desired syrup is prepared by adding sugar. The product will be stored in a sterile glass container and closed until dark, in the dark and in the refrigerator at 4 ° C. At a dose of 3 cc daily for 6 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Artesh 505 Hospital

##### Full name of responsible person

Mohammadreza ghasemzadeh

##### Street address

The end of Avshan Boulevard, Artesh Boulevard, Aqdasiyeh

##### City

Tehran

##### Province

Tehran

##### Postal code

4414119569

##### Phone

+98 21 2248 1806

##### Email

m.rezaghasemzadeh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Mojtaba Yousefi Zoshk

##### Street address

Aja University of Medical Sciences, Shaheed Etemadzadeh St, West Fatemi Blvd

##### City

Tehran

##### Province

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##### Postal code

1411718541

##### Phone

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##### Email

Dr.yousefi.md@ajaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Artesh 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

Artesh University of Medical Sciences

##### Full name of responsible person

Mohammadreza Ghasemzadeh

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

505 hospital, Oshan Blvd, Artesh Highway, Tehran, Iran

##### City

Tehran

##### Province

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##### Postal code

1956944141

##### Phone

+98 21 2248 1806

##### Fax

##### Email

m.rezaghasemzadeh@yahoo.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Mohammadreza Ghasemzadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Mohammadreza Ghasemzadeh

**Position**

Assistant professor

**Latest degree**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to  
make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available