

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

the therapeutic effect of Eugenia Caryophyllat,s product in patients with depression

Protocol summary

Study aim

Effectivnese of Clove in treatment of depression

Design

The possibility of using randomization in different groups of installation and holder placement was provided by Beck questionnaire at 0,2,4,6 weeks using questionnaaire

Settings and conduct

Patient admission in Sari Psychiatric Clinics and Imam Hossein Hospital in Sari Patients with the Stritified Block Randomization method will be divided into two groups of 30 interventions and placebo. And blinding is two-way, and the drug capsule and control are similar, and patients and researchers are not aware of their type.

Participants/Inclusion and exclusion criteria

- 1.consent form
- 2.Age between 18 and 65 years
- 3.diagnose of depression disorder based on DSM5 and supervised for 6weeks
- Exclusion: 1.The symptoms of high mood 2.Suicidal thoughts 3.Drug side effects 4.Pregnancy and breastfeeding

Intervention groups

Intervention Group: Eugenia Caryophyllat,s product (Clove capsule) receive one capsule BD+ S Citalopram 20mg daily Control group:placebo receive one capsule BD+ S Citalopram 20mg daily

Main outcome variables

score of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190309042979N1**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

bita sadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4001

Email address

b.sadeh@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-22, 1398/02/02

Expected recruitment end date

2020-04-02, 1399/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the therapeutic effect of Eugenia Caryophyllat,s product in patients with depression

Public title

The effect of Eugenia Caryophyllat,s product on depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1-Declaration of written consent of the candidate for

participation 18-65 years old Detection of major depressive disorder based on DSM-5 and treated for more than 6 weeks Score 14 to 28 in the depression test 21 BDI-II questions

Exclusion criteria:

symptoms of high mood suicide incidence The incidence of unknown side effect patient request pregnancy and lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation to intervention and control groups Stratified Block Randomization Random number table Patients with Stritified Block Randomization will be divided into two groups of 30 interventions and placebo. In this method, the group of mild to moderate depressed patients is classified as stritified. By randomly selecting the block, the number of patients is determined and the type of intervention is determined using closed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug of Intervention and placebo ,are coded in the envelope, patient and researcher and physician none of them don t know about them.drug and placebo are the same in colour and size and smell

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

Khazar street

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.MAZUMS.REC.1398.302

Health conditions studied

1

Description of health condition studied

Major depressive disorder, single episode, moderate

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

2

Description of health condition studied

Major depressive disorder, single episode, mild

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

Depression Score

Timepoint

Before the start of the intervention (week 0) and 14, 28 and 42 days after the start of the intervention

Method of measurement

Beck questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Eugenia Caryophyllat,s product + S Citalopram - In this group, routine S-Sitalopram 20mg treatment daily one tablet plus clove product (Clove capsule) receive one capsule BD

Category

Treatment - Drugs

2

Description

Control group:placebo+s citalopram - In this group, routine treatment with 20 mg of s citalopram routine plus one pill daily plus placebo (placebo capsule) receive one capsule BD

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hossein hospital

Full name of responsible person

Dr jamal shams

Street address

Madani street

City

Tehran

Province

Tehran

Postal code

16177633141

Phone

+98 21 7755 8001

Fax

+98 21 7343 2396

Email

info@ehmc.ir

Web page address

<http://www.ehmc.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

Moalem Square. Deputy of research and technology.
Mazandaran University of Medical Sciences

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publicrel@mazums.ac.ir

Web page address

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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

Assie Jokar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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