

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the efficacy of oral administration of Cinnamomum tamala with placebo in patients with depressive disorder

Protocol summary

Study aim

Investigating the Effect of cinnamomum tamala on depression

Design

In this study, 50 patients with Major depression and Inclusion criteria referred to Tehran Psychiatric Institute are selected. The participants are randomly divided into intervention and control groups. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

Tehran Psychiatric Institute

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Patients have MDD(Major Depression) diagnosis based on DSM5 and the maximum severity of depression is equal or higher than 18 in the Hamilton Depression Scale. Exclusion criteria: the presence of psychotic symptoms; the presence of another psychiatric disorder; receiving psychotropic drugs; receiving antidepressants in the past month and ECT in the last two months; hypothyroidism; history of cardiovascular disease, pregnancy or lactation

Intervention groups

Intervention: 25 people take 250 mg of cinnamomum tamala daily with Sertraline Control group: 25 people take 250 mg of the placebo daily with Sertraline

Main outcome variables

Severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037889N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **prospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

saloumeh ghafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5515 2192

Email address

ghaffari.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-29, 1396/11/09

Expected recruitment end date

2018-06-30, 1397/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of oral administration of Cinnamomum tamala with placebo in patients with depressive disorder

Public title

Cinnamomum tamala in the treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: presence of Major Depressive Disorder based on DSM-5 criteria baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 18 18-60 years old

Exclusion criteria:

Exclusion criteria: presence of psychosis any other diagnosis in axis I and II; receiving psychotropic medications receiving any antidepressants during past one month or ECT during past two months; hypothyroidism cardiovascular problems pregnancy or nursing women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to intervention and control groups based on simple randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are randomly divided into two groups and receive drug box with the same shape and size but different content,each patient is advised to take an oral capsule daily,the patient, the physician who will examine the patients and appraiser of them will not be aware of the contents of the drug containers.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, Hemat Highway, Iran University of Medical

Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-12-11, 1396/09/20

Ethics committee reference number

IR.IUMS.REC1396.9321309004

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

Depression

ICD-10 code

F32

ICD-10 code description

Major Depressive Disorder

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

Depression score in Hamilton Test

Timepoint

2,4,6

Method of measurement

Hamilton Depression Test

Secondary outcomes**1****Description**

Drug side effects

Timepoint

1,2,4,6,Weeks

Method of measurement

Drug side effects questionnaire

Intervention groups**1****Description**

Intervention group: cinnamomum tamala 250-500 mg daily plus sertraline 50-100 mg / day

Category

Treatment - Drugs

2**Description**

Control group: Placebo 250-500 mg daily with sertraline 50-100 mg / day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Psychiatric Institute

Full name of responsible person

Saloumeh Ghaffari

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Faculty of Iranian Medicine, Behesht Street, Hassan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakoti

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Iran University of Medical Sciences, Besides Milad
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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Saloumeh Ghaffari

Position

Student of PHD

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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