# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 than18in 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 Sertralin Control group:25people take 250 mg of the plasebo daily with Sertralin
**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
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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 Abad Square,Tehran

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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

**Street address**
Iran University of Medical Sciences,Besides Milad Tower,Hemmat Highway,Tehran

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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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