

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

L-Theanine as an adjuvant therapy in the treatment of major depressive disorder: a double-blind, randomized, placebo-controlled clinical trial

Protocol summary

Study aim

Investigating the effect of L-Theanine on the treatment of major depressive disorder

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be conducted among patients with major depressive disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of major depressive disorder, based on DSM-5 - Age between 18 to 60 years - The minimum score of 19, based on Hamilton depression scale. Exclusion criteria: Drug use during 1 year prior to trial (except nicotine) - Receive psychotropic drugs during 1 month prior to trial - History of Electroconvulsive therapy, two months prior to the trial - Psychosis - History of at least one period of mania or hypomania or mixed - Serious suicidal thoughts (The score of >2 in Hamilton depression scale, the suicidal tendencies section) - Kidney, liver, cardiovascular, or thyroid disorders - Pregnant or lactating women - Presence of concomitant psychiatric disorders - The patient's own request to leave the study

Intervention groups

Patients with major depression (based on DSM-5 diagnostic criteria) are included in the study and divided into two control (25 participants) and intervention (25 participants) groups. Patients in the intervention group receive Sertraline tablet 100 mg per day + L-Theanine tablet 200 mg per day, and patients in the control group receive Sertraline tablet 100 mg per day + placebo (for 6 weeks). Patients are evaluated at weeks 0, 2, 4, and 6 by the Hamilton Depression Rating Scale.

Main outcome variables

Severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N131**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **prospective**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L-Theanine as an adjuvant therapy in the treatment of major depressive disorder: a double-blind, randomized, placebo-controlled clinical trial

Public title

L-Theanine as an adjuvant therapy in the treatment of major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of major depressive disorder, based on DSM-5
Age between 18 to 60 years
The minimum score of 19, based on Hamilton depression scale

Exclusion criteria:

Drug use during 1 year prior to trial (except nicotine)
Receive psychotropic drugs during 1 month prior to trial
History of Electroconvulsive therapy, two months prior to the trial
Psychosis History of at least one period of mania or hypomania or mixed
Serious suicidal thoughts (The score of >2 in Hamilton depression scale, the suicidal tendencies section)
Kidney, liver, cardiovascular, or thyroid disorders
Pregnant or lactating women
Presence of concomitant psychiatric disorders
The patient's own request to leave the study

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B interventions in blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

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 University of Medical Sciences, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.TUMS.VCR.REC.1398.1011

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description

Severity of depression

Timepoint

Baseline and weeks 2, 4, and 6

Method of measurement

By Hamilton depression scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sertraline tablet (Sobhan co.) 100 mg per day + L-Theanine tablet (ACECR) 200 mg per day for

6 weeks
Category
Treatment - Drugs

2

Description

Control group: Sertraline tablet (Sobhan co.) 100 mg + placebo tablet per day for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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Phone

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mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

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msahrai@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2021 to 2026

To whom data/document is available

academic researchers

Under which criteria data/document could be used

users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

Comments