

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

L-Theanine combination therapy with Fluvoxamine in moderate to severe obsessive-compulsive disorder: A placebo-controlled, double-blind, randomized trial

Protocol summary

Study aim

L-Theanine combination therapy with Fluvoxamine in the treatment of moderate to severe obsessive-compulsive disorder

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be performed on patients with moderate to severe obsessive-compulsive disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 to 60 years old; diagnosis of moderate to severe OCD based on DSM-5; score of >21 in Yale-Brown obsessive-compulsive scale (Y-BOCS). Exclusion criteria: receiving any treatment up to 6 weeks before the start of the trial; presence of another psychiatric disorder.

Intervention groups

Patients with moderate to severe obsessive-compulsive disorder (based on DSM-5 diagnostic criteria) are included in the study and divided into two control (25 participants) and intervention (25 participants) groups. All patients are treated with Fluvoxamine 100 mg daily for the first four weeks and then 200 mg daily until the end of the tenth week. L-Theanine 100 mg twice/day will be given to patients. In the control group, patients will receive a placebo, twice/day. Patients are evaluated at weeks 0, 5, and 10 by Yale-Brown obsessive-compulsive scale (Y-BOCS).

Main outcome variables

Severity of obsessive-compulsive disorder (OCD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N134**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **prospective**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L-Theanine combination therapy with Fluvoxamine in moderate to severe obsessive-compulsive disorder: A placebo-controlled, double-blind, randomized trial

Public title
L-Theanine for the treatment of obsessive-compulsive disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 60 years Diagnosis of moderate to severe OCD based on DSM-5 Score of >21 in Yale-Brown obsessive-compulsive scale (Y-BOCS)
Exclusion criteria:
Receiving any treatment up to 6 weeks before the start of the trial Presence of another psychiatric disorder

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 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, Qhods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-08-21, 1399/05/31
Ethics committee reference number
IR.TUMS.DDRI.REC.1399.023

Health conditions studied

1

Description of health condition studied
Obsessive-compulsive disorder

ICD-10 code
F42

ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
Severity of OCD symptoms

Timepoint
Baseline and weeks 5 and 10

Method of measurement
By Yale-Brown obsessive-compulsive scale (Y-BOCS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Fluvoxamine tablet (Sobhan darou co.) 100 mg daily for the first 4 weeks and 200 mg daily for the next 6 weeks + L-Theanine (Institute of Medicinal Plants) tablet 100 mg BID, for 10 weeks

Category
Treatment - Drugs

2

Description
Control group: Fluvoxamine tablet (Sobhan darou co.)

100 mg daily for the first 4 weeks and 200 mg daily for the next 6 weeks + Placebo tablet BID, for 10 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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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

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Name of organization / entity

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Web page address

Person responsible for updating data

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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