Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-Theanine100 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
s.akhond@sina.tums.ac.ir

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

City
Tehran

Province
Tehran

Postal code
1333715914

Phone
+98 21 5541 2222

Email
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.

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 8898 7381

Email
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

Street address
Roozbeh Hospital, South Kargar Street, Tehran

City
Tehran

Province
Tehran

Postal code
1333715914

Phone
+98 21 5541 2222

Email
s.akhond@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Prof. Shahin Akhondzadeh

Position
Professor of clinical psychopharmacology

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Roozbeh Hospital, South Kargar Street, Tehran

City
Tehran

Province
Tehran

Postal code
1333715914

Phone
+98 21 5541 2222

Email
s.akhond@sina.tums.ac.ir

Web page address

Person responsible for updating data

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

Street address
Roozbeh Hospital, South Kargar Street, Tehran

City
Tehran

Province
Tehran

Postal code
1333715914

Phone
+98 21 5541 2222

Email
s.akhond@sina.tums.ac.ir

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