Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

5-hydroxytryptophan combination therapy with fluoxetine in the treatment of moderate to severe OCD: a double blind randomized trial with placebo control

Protocol summary

Study aim
The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of 5-hydroxytryptophan would improve psychopathology in subjects with OCD treated with fluoxetine
Design
randomized, double-blind, placebo controlled study
Settings and conduct
The study will be conducted among patients attending Roozbeh Hospital-Tehran
Participants/Inclusion and exclusion criteria
1- Age between 18-60 years old; 2- Diagnosis of OCD based on DSM-5; 3- Minimum Score of 21 on YALE-BROWN Obsessive-Compulsive Scale
Intervention groups
Fluoxetine 60 mg per day+ 5-hydroxytryptophan100mg BID for 12 weeks as intervention group
Main outcome variables
Severity of symptoms of OCD

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090117001556N106**
Registration date: **2018-04-05, 1397/01/16**
Registration timing: **prospective**

Last update: **2018-04-05, 1397/01/16**
Update count: **0**
Registration date
2018-04-05, 1397/01/16

Registrant information
Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-19, 1397/01/30
Expected recruitment end date
2020-04-18, 1399/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
5-hydroxytryptophan combination therapy with fluoxetine in the treatment of moderate to severe OCD: a double blind randomized trial with placebo control

Public title
5-hydroxytryptophan in treatment of moderate to severe OCD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-60 years old Diagnosis of OCD based on DSM-5 inimum Score of 21 on YALE-BROWN Obsessive-

Compulsive Scale

Exclusion criteria:

Substance dependence IQ less than 70 Any other mental disorder Any serious cardiac, renal or hepatic disease receiving psychotropic medications during the last 6 weeks pregnancy or breast feeding Rising liver transaminases to three times the upper limit of normal or higher

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks (each block has four cases)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, clinicians and outcome evaluators will be blind regarding grouping

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

كميته اخلاق دانشگاه علوم پزشكي تهران

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-03-10, 1396/12/19

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4661

Health conditions studied

1

Description of health condition studied

Obsessive- Cumpulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Severity of symptoms of OCD

Timepoint

Baseline and weeks: 4, 8, 12 after beginnig of treatment

Method of measurement

Y_BOCS(Yale-Brown obsessive compulsive scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fluoxetine 60 mg/day+ 5-hydroxytryptophan 100 mg BID for 12 weeks as intervention group

Category

Placebo

2

Description

Control group: Fluoxetine 60mg per day + placebo for 12 weeks as control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
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
Prof. of Clinical Psychopharmacology
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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

No - There is not 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

All data will be distributed through final report

When the data will become available and for how long

from 2021 to 2026

To whom data/document is available

academic researchers

Under which criteria data/document could be used

by email

From where data/document is obtainable

prof Shahin Akhondzadeh

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

s.akhond@sina.tums.ac.ir

Comments