Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

L-Carnosine as adjuvant therapy in the treatment of moderate to severe OCD: a double blind randomized trial with placebo control

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of L-Carnosine would improve psychopathology in subjects with OCD treated with fluvoxamine. 50 patients with chronic DSM-5- diagnosed OCD will receive fluvoxamine (100 mg/day) combined with either placebo (N=25) or500 mg/day L-Carnosine (N=25) for 10 weeks. Patients will be assessed by a psychiatrist at baseline and after 2, 4 ,6,8 and 10 weeks after the medication started. OCD severity will be assessed by b the Yale-Brown obsessive compulsive scale(Y-B ocs)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604201556N88**
Registration date: **2016-04-21, 1395/02/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-04-21, 1395/02/02

Registrant information

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Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-08-05, 1395/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L-Carnosine as adjuvant therapy in the treatment of moderate to severe OCD: a double blind randomized trial with placebo control

Public title

L-Carnosine in the treatment of OCD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-Age between 18-60years old; 2- Diagnosis of OCD based on DSM V; 3- Minimum Score of 21 on YALE-BROWN Obsessive-Compulsive Scale.
Exclusion Criteria: 1- Substance dependence; 2- IQ <70; 3- Any other mental disorder on axis I; 4-Any serious cardiac, renal or hepatic disease; 5- receiving psychotropic medications during the last 6 weeks; 6- pregnancy or breast feeding; 7- 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

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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, Keshvarz Blvd

City

Tehran

Postal code

Approval date

2016-04-19, 1395/01/31

Ethics committee reference number

IR.TUMS.REC.1395.2437

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: 2, 4, 6, 8, 10 after beginig of treatment

Method of measurement

Y_BOCS(Yale-Brown obsessive compulsive scale)

Secondary outcomes

empty

Intervention groups

1

Description

Fluvoxamine 100 mg/day+ L-Carnosine 500mg/day for 10 weeks as intervention group

Category

Treatment - Drugs

2

Description

Fluvoxamine 100 mg/day + placebo for 10 weeks as control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Sreeet

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

Tehran University of Medical Sciences, Keshvarz Blvd.

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Prof. Shahin Akhondzadeh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty