

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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) or 500 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 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

##### 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

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- Compulsive 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 Sreet

##### 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*

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S.akhond@sina.tums.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Roozbeh Hospital, South Kargar Sreet

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Roozbeh Hospital, South Kargar Sreet

**City**

Tehran

**Postal code****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*