

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Saffron in the treatment of mild to moderate OCDL a randomised , double blind and controlled trial

#### Protocol summary

##### Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of saffron would improve psychopathology in subjects with OCD treated with fluvoxamine. 50 patients with chronic DSM-V- diagnosed OCD will receive fluvoxamine (100 mg/day) (N=25) or 15 mg bid Saffron (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: **IRCT201407151556N62**

Registration date: **2014-07-17, 1393/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-07-17, 1393/04/26

##### 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

2014-08-01, 1393/05/10

##### Expected recruitment end date

2016-07-30, 1395/05/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Saffron in the treatment of mild to moderate OCDL a randomised , double blind and controlled trial

##### Public title

Saffron in the treatment of OCDL a randomised

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1-Age between 18-60 years 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 diseases; 5- Receiving psychotropic medications during the last 6 weeks; 6- Pregnancy or breast feeding.

##### Age

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

##### Gender

Both

##### Phase

3

##### Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

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

2014-06-22, 1393/04/01

#### Ethics committee reference number

25406

## 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 2-4-8-10 after beginig of treatment

#### Method of measurement

Y\_BOCS

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Fluvoxamine 100 mg/day 10 weeks as intervention group

#### Category

Treatment - Drugs

### 2

#### Description

Saffron 15 mg twice per day for 10 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Roozbeh Hospital

##### Full name of responsible person

Prof. Shahin Akhondzadeh

##### Street address

Roozbeh Hospital, South Kargar street

##### 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

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

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

Roozbeh Hospital, South Kargar street

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

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**City**

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**Postal code****Phone**

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**Fax**

## 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*