Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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- 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 2-4-8-10 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
City
Tehran
Postal code
Phone
+98 21 5541 2222
Fax
Email
S.akhond@sina.tums.ac.ir
Web page address

Person responsible for scientific 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
City
Tehran
Postal code
Phone
+98 21 5541 2222
Fax
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
Prof. Shahin Akhondzadeh
Position
Prof. of Clinical Psychopharmacology
Other areas of specialty/work
Street address
Roozbeh Hospital, South Kargar street
City
Tehran
Postal code
Phone
+98 21 5541 2222
Fax
Email
S.akhond@sina.tums.ac.ir
Web page address

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