Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Tropisetron as an Adjuvant Therapy for Obsessive-compulsive Disorder: A Double-blind, Placebo-controlled, Randomized Trial

Protocol summary

Summary

Obsessive-Compulsive Disorder (OCD) is known by recurrent and intrusive dystressfull thoughts, images and impulses(obsessions) and recurrent and goal-directed behaviors that patient has to do those(Compulsive). Pharmacological treatment by Selective-Serotonin Re-uptake Inhibitors(SSRIs) and a Tricyclic Anti-Depressant (Clomipramine) is effective for this condition, but 20% of patients are known as treatment-resistant and 20-30% of them show relative response. It seems that addition of a 5HT3 antagonist such as Ondansetrone and Granisetrone to a SSRI has potential efficacy. Therefore with have decided to evaluate efficacy and safety of another member of this drug group, Tropisetrone, for treatment of OCD. This study will perform as a randomized double-blind clinical trial in 10 weeks. 50 outpatient who meet DSM-IV-TR criterion of OCD by structured clinical interview will be divided randomly into 2 arms (one will be treated by Tropisetrone 5mg daily and Fluvoxamine 100mg for 4 first weeks and 200 upcoming weeks, another will be treated by similar pattern and dosage of Fluvoxamine and Placebo). Participants will be evaluated by YBOCS and drug side effects checklist in 0,4,8,10 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012332145N1**
Registration date: **2017-02-13, 1395/11/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

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Mohammadreza Shalbafan
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Tropisetron as an Adjuvant Therapy for Obsessive-compulsive Disorder: A Double-blind, Placebo-controlled, Randomized Trial

Public title

Tropisetron for treatment of Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Patients who meet DSM-IV-TR criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be

18-60 years old and sign consent form. they should not be treated by any psychiatric interventions for 6 weeks ago. If they show any other mental important conditions or suicidal thoughts, neurological deficits, exclude from study. They will evaluate for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

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)
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
Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran

City
Tehran

Postal code

Approval date
2016-12-28, 1395/10/08

Ethics committee reference number
IR.IUMS.REC.1395.95-03-121-29352

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 obsessive-compulsive disorder

Timepoint
Weeks: 0, 4, 8 and 10

Method of measurement
Yale-Brown Obsessive Compulsive Scale(YBOCS)

Secondary outcomes

1

Description
Side effects

Timepoint
Weeks: 0, 4, 8 and 10

Method of measurement
Checklist

Intervention groups

1

Description
Tropisetrone capsul 5mg daily and Fluvoxamine tablet 100mg daily for 4 first weeks and 2 per day for upcoming weeks. Oral ingestion is route of prescription.

Category
Treatment - Drugs

2

Description
Placebo capsul daily and Fluvoxamine tablet 100mg daily for 4 first weeks and 2 per day for upcoming weeks. Oral ingestion is route of prescription.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Psychiatry Hospital

Full name of responsible person
Dr Mohammadreza Shalbafan

Street address
Tehran-Karaj 7 km, Tehran

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2

Recruitment center

Name of recruitment center
Tehran Psychiatry Institute
Full name of responsible person
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Recruitment center
Name of recruitment center
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Full name of responsible person
Dr Shahin Akhondzadeh
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4

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Dr Seyed Ali Dastgheyb
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5

Recruitment center
Name of recruitment center
Zahedan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Shalbafan
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
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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
Iran 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

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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