

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 distressful thoughts, images and impulses (obsessions) and recurrent and goal-directed behaviors that patient has to do those (Compulsive). Pharmacological treatment by Selective-Serotonin Reuptake 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 Ondansetron and Granisetron to a SSRI has potential efficacy. Therefore we have decided to evaluate efficacy and safety of another member of this drug group, Tropisetron, 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 Tropisetron 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

Name

Mohammadreza Shalbafan

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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**

Tropisetron 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

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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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3**Recruitment center****Name of recruitment center**

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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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Shiraz

5**Recruitment center****Name of recruitment center**

Zahedan University of Medical Sciences

Full name of responsible person

Dr Zahra Ghiasi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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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****Contact****Name of organization / entity**

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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