

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of therapeutic effect of Topiramate augmentation in refractory Obsessive- Compulsive Disorder

Protocol summary

Summary

This study is a double blind placebo-controlled randomized clinical trial according to inclusion criteria (having Obsessive Compulsive Disorder with Yale Brown Scale score more than 16 despite using of Selective Serotonin Reuptake Inhibitor or Clomipramine for at least 8 to 12 weeks with maximum tolerated dose) and exclusion criteria (past history of renal stone or having psychotic or mood disorder) 32 patient with refractory Obsessive Compulsive Disorder who referred to Isfahan Obsessive Compulsive Disorder clinics of Nour hospital randomly divided to two groups, cases and controls. Case group would be prescribed Topiramate and control group would be prescribed placebo and also two groups would continue their previous drugs (Selective Serotonin Reuptake Inhibitor and/or Clomipramine). Patients would be followed for 12 weeks before intervention and after 1, 2 and 3 months they would be evaluated using Yale Brown Scale and Clinical Global Impressions.

General information

Acronym

OCD

IRCT registration information

IRCT registration number: **IRCT2013012312252N1**

Registration date: **2013-02-18, 1391/11/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-18, 1391/11/30

Registrant information

Name

Elham Zarean

Name of organization / entity

Isfahan University Of Medical Science

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Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2013-02-03, 1391/11/15

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of Topiramate augmentation in refractory Obsessive- Compulsive Disorder

Public title

Therapeutic effect of Topiramate in refractory Obsessive Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Obsessive Compulsive criteria according to DSM-IV-TR; Be used maximum tolerated dose of SSRI or Clomipramine for at least 12 weeks; moderate to severe symptoms according to Yale Brown Scale score more than 16; informed consent Exclusion criteria: primary diagnosis of psychotic or mood disorder (bipolar or MDD); substance abuse or

dependence; uncontrolled medical illness(e.g. DM,HTN,...); previous use of Topiramate; pregnancy or breastfeeding or who wants to be pregnant; convulsive disorder; suicidal thought; past history of renal stone

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

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**

Isfahan University Of Medical Science

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Isfahan University Of Medical Science1, Daneshgah Bol

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8174673441

Approval date

2012-06-13, 1391/03/24

Ethics committee reference number

391144

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**

Obsessive Compulsive Disorder severity

Timepoint

before intervention and after first,second and third month

Method of measurement

Yale Brown Scale and CGI scale

Secondary outcomes

empty

Intervention groups**1****Description**

Tablet Topiramate 25 mg would be prescribed daily and increased 25mg weekly with respect to patient tolerance.Treatment would be continued for 3 months

Category

Treatment - Drugs

2**Description**

Tablet Placebo 25 mg would be prescribed daily and increased 25mg weekly with respect to patient tolerance.Treatment would be continued for 3 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Shariati Clinic of Psychiatry

Full name of responsible person

Dr SHahla Akuchekian

Street address**City**

Isfahan

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

Isfahan University Of Medical Sciences

Full name of responsible person

Mr Toghyani

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City

Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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