Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 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). paitients would be followed for 12 weeks.before intervention and after 1,2 and 3 month 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

Country

Iran (Islamic Republic of)

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+98 31 1668 0048

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e_zarean@resident.mui.ac.ir

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); subtance 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

Street address
Isfahan University Of Medical Sciencel, Daneshgah Bol

City
Isfahan

Postal code
8174673441

Approval date
2012-06-13, 1391/03/24

Ethics committee reference number
391144

Health conditions studied

1

Description of health condition studied
Obcessive 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

Street address
Isfahan University Of Medical Sciences, Daneshgah Bol

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

Contact

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

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Position

residant

Other areas of specialty/work

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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