Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of treatment of bipolar disorder (lithium + olanzapine + clonazepam) and placebo with a treatment regimen containing topiramate in controlling the OCD symptoms of bipolar patients

Protocol summary

Summary

Regarding the high comorbidity of Obsessive - Compulsive Disorder(OCD) with Bipolar Mood Disorder(BMD) and problems in the treatment of BMD patients (conventional treatment for OCD, may worsen the underlying disease), this study intends to control the effects of topiramate in BMD patients with obsessive-compulsive symptoms compared with the placebo.The population under study is the patients with bipolar mood disorder who will refer to clinics and hospitals of Shiraz University of Medical Sciences. Each group will consist of 16 patients, one of them will receive topiramate in addition to lithium, olanzapine and clonazepam and other group will given placebo and same drugs for 16 weeks. Patients in both groups one and two will chosen through randomly assigned numbers by the trial executive and both the key partner and the patients will be unaware of the treatment. Assess the severity of obsessive-compulsive symptoms in the week zero will done by the trial executive by Y-BOCS (Yale - Brown Obsessive Compulsive Scale)questionnaire and key partner will follow patients next weeks.Drug Side effects based on the drug side effects checklist and changes in the obsessive - compulsive symptoms, based on Y-BOCS questionnaire will assessed at weeks 2,4,8,12,16. Dose of lithium, olanzapine, and clonazepam will sufficient for patients symptoms control. Topiramate Begins with an initial dose of 25mg/day and 25mg a week adds up to 200mg/day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061310013N1**
Registration date: **2012-10-05, 1391/07/14**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-10-05, 1391/07/14

Registrant information

Name
Mohamad Bigdeli
Name of organization / entity
Shiraz University of Medical ScienceS
Country
Iran (Islamic Republic of)
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+98 71 1627 9319
Email address
bigdelim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment of bipolar disorder (lithium + olanzapine + clonazepam) and placebo with a treatment regimen containing topiramate in controlling the OCD symptoms of bipolar patients

Public title

Comparison of topiramate and placebo in controlling the OCD symptoms of bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Fulfilling DSM-IV-TR criteria for bipolar mood disorder; have not Major medical problem (cardiovascular, respiratory, renal or gastrointestinal disease); not pregnant; not alcohol or other substances abuser; scores >= 18 in Yale- Brown Obsessive Compulsive Scale questionnaire. Exclusion criteria; failure to cooperate in the ongoing project for the periodical visits; non-qualification for inclusion criteria.

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

Local Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Blvd., Shiraz

City

Shiraz

Postal code

Approval date

2012-05-12, 1391/02/23

Ethics committee reference number

CT -91 -2461

Health conditions studied

1

Description of health condition studied

Bipolar Mood Disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder, current episode hypomanic

2

Description of health condition studied

Obsessive-Compulsive disorder

ICD-10 code

F42

ICD-10 code description

Predominantly obsessional thoughts or ruminations

Primary outcomes

1

Description

obsessive-compulsive signs&symptoms in BMD patients

Timepoint

before intervention and then monthly for 4 months

Method of measurement

Yale- Brown Obsessive Compulsive Scale questionaire

Secondary outcomes

1

Description

drug side effects

Timepoint

monthly for 4 months

Method of measurement

checklist of drug side effects

Intervention groups

1

Description

16 patient intervention group will recieve topiramate in addition to lithium,olanzapine and clonazepam for 16 weeks.Dose of lithium, olanzapine, and clonazepam will sufficient for patients symptoms control. Topiramate Begins with an initial dose of 25mg/day and 25mg a week adds up to 200mg/day.

Category

Treatment - Drugs

2

Description

16 patients control group will recieve placebo in addition to lithium,olanzapine and clonazepam for 16 weeks.Dose of lithium, olanzapine, and clonazepam will sufficient for patients symptoms control.placebo Begins with an initial dose of 25mg/day and 25mg a week adds up to

200mg/day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn-e-Sina Hospital

Full name of responsible person

Mohamad Bigdeli , MD

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Mohamad Bigdeli , MD

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam, Phd

Street address

Central Building of Shiraz University of Medical Sciences, Zand Blvd., Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Psychiatry department of Shiraz University of Medical Sciences

Full name of responsible person

Ali Sahraian, MD

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Psychiatry department of Shiraz University of Medical Sciences

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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