Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of lithium and topiramate with lithium and placebo in patients with bipolar I disorder most recent manic episode

Protocol summary

Summary

We try to show the efficacy of adjunctive topiramate in acute mania in a randomized, double-blind, placebo-controlled study. Patients, aged 18 and over suffering from bipolar I disorder most recent manic episode hospitalized in Razi Psychiatric Hospital, are randomly selected and divided into two groups, control and intervention. The possible risks and benefits of treatment with topiramate would be explained to patients and relatives and a written informed consent is obtained. Using Cohen Statistical Power Analysis, 23 patients are going to be allocated to each group in a double-blind manner. In intervention group patients would receive 900mg/day of lithium carbonate and 2mg/day of risperidone (may be increased if needed to 8mg/day) or equivalent dose of other antipsychotics plus topiramate starting with 50 mg/day and increasing the dose 50 mg each 3 days to reach the maximum dose of 200 mg/day. In control group patients would receive 900mg/day of lithium carbonate and 2mg/day of risperidone (may be increased if needed to 8mg/day) or equivalent dose of other antipsychotics plus placebo. Patients are being interviewed weekly by a psychiatric resident and the response to treatment would be assessed at the baseline and weekly, using YMRS. Compliance, appetite, weight and suicidal ideas and side effects of topiramate and symptoms and signs of lithium toxicity would be assessed in every interview. In the first visit the height and weight would be measured and accordingly BMI is recorded. Duration of the study is 6 weeks after reaching the optimal dose of topiramate which is 200mg/day (8 weeks).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110317960N1**

Registration date: **2011-12-09, 1390/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-09, 1390/09/18

Registrant information

Name

Zahra Mirsepassi

Name of organization / entity

University of social welfare and rehabilitation sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8808 2585

Email address

za.mirsepassi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2011-07-30, 1390/05/08

Expected recruitment end date

2012-07-29, 1391/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of lithium and topiramate with lithium and placebo in patients with bipolar I disorder most recent manic episode

Public title

Efficacy of adjunctive topiramate in acute mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) age 18 and over; 2) bipolar I disorder most recent manic episode (according to DSMIV-TR criteria). Exclusion criteria: 1) pregnant woman; 2) lactating woman; 3) presence of disabling medical or neurologic disease; 4) history of kidney disease; 5) history of renal stone; 6) history of hypersensitivity to topiramate.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **46**

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

Unuversity of social welfare and rehabilitation sciences

Street address

Koodakyar, Evin

City

Tehran

Postal code

Approval date

2011-11-22, 1390/09/01

Ethics committee reference number

801/A/2/15497

Health conditions studied

1

Description of health condition studied

bipolar I disorder most recent manic episode

ICD-10 code

F32.1

ICD-10 code description

Moderate depressive episode

2

Description of health condition studied

bipolar I disorder most recent manic episode

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

efficacy of adjunctive topiramate in acute mania

Timepoint

after 8 weeks

Method of measurement

YMRS

Secondary outcomes

1

Description

appetite

Timepoint

after 8 weeks

Method of measurement

interview

2

Description

weight

Timepoint

after 8 weeks

Method of measurement

according to weight

3

Description

side effects of topiramate

Timepoint

after 8 weeks

Method of measurement

interview

4

Description

suicidal ideas

Timepoint

after 8 weeks

Method of measurement

interview

5

Description
compliance
Timepoint
after 8 weeks
Method of measurement
interview and nursing records

6

Description
lithium toxicity
Timepoint
after 8 weeks
Method of measurement
interview and physical examination

Intervention groups

1

Description
In intervention group patients would receive 900mg/day of lithium carbonate and 2mg/day of risperidone (may be increased if needed to 8mg/day) or equivalent dose of other antipsychotics plus topiramate starting with 50 mg/day and increasing the dose 50 mg each 3 days to reach the maximum dose of 200 mg/day.
Category
Treatment - Drugs

2

Description
In control group patients would receive 900mg/day of lithium carbonate and 2mg/day of risperidone (may be increased if needed to 8mg/day) or equivalent dose of other antipsychotics plus placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Psychiatric Hospital
Full name of responsible person
Zahra Mirsepassi
Street address
City
Shahre Rey

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Zahra Mirsepassi
Street address
Koodakyar, Evin
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University ofsocial welfarw and rehabilitation sciences
Full name of responsible person
Zahra Mirsepassi
Position
psychiatric resident
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Web page address

Person responsible for updating data

Contact

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