

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Gabapentin as a combination treatment with lithium in adolescents with bipolar disorder: a double-blind, randomized, placebo-controlled clinical trial

Protocol summary

Summary

There are some studies about the role of Gabapentin in the treatment of bipolar disorder in adults. So this study is designed to investigate the efficacy of combined Gabapentin and lithium in youths with bipolar disorder. Method: In a 8 week , double - blind clinical trial, 31 adolescents with a diagnosis of bipolar disorder are randomized into treatment with lithium plus Gabapentin (n=16) or lithium plus placebo (n=15) . The primary outcome measure is young mania rating scale score. Anxiety and depression will be measured biweekly with Hamilton rating scale and Beck depression inventory. Weight and side effects also are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010172000N4**
Registration date: **2010-10-20, 1389/07/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-20, 1389/07/28

Registrant information

Name

Rozita Davari Ashtiani

Name of organization / entity

Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 7755 1023

Email address

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Recruitment status

Recruitment complete

Funding source

Behavioral sciences research center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2007-12-22, 1386/10/01

Expected recruitment end date

2009-04-19, 1388/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Gabapentin as a combination treatment with lithium in adolescents with bipolar disorder: a double-blind, randomized, placebo-controlled clinical trial

Public title

Gabapentin in bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1)10 -17 years of age 2) score more than 20 in Young Mania Rating Scale (YMRS, Yongstorm , et al, 2003) 3)not being on any psychiatric medication for at least two weeks prior to entry into this trial 4) signing a written informed consent. Exclusion criteria: 1) any significant medical illness, 2) IQ lower than70, 3) meeting criteria for substance dependence and abuse in the month before trial

Age

From **10 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 31

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**

Shahid Beheshti university of Medical Sciences,
Behavioral Sciences research Center

Street address

Imam Hossein Hospital, Shahid Madani st, Tehran

City

Tehran

Postal code**Approval date**

2009-02-02, 1387/11/14

Ethics committee reference number

5949

Health conditions studied**1****Description of health condition studied**

bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes**1****Description**

mania severity

Timepoint

before intervention and every two weeks

Method of measurement

Young Mania rating Scale

Secondary outcomes**1****Description**

anxiety severity

Timepoint

before intervention and every two weeks

Method of measurement

Hamilton rating scale

2**Description**

depression severity

Timepoint

before intervention and every two weeks

Method of measurement

Beck Depression Inventory

3**Description**

side effects

Timepoint

on weeks 2,4,6,8

Method of measurement

side effects checklist

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

Intervention: lithium at doses producing a serum concentration of 0.8-1 meq/l + GBP with a target daily dose of 400mg/day

Category

Treatment - Drugs

2**Description**

Control: lithium at doses producing a serum concentration of 0.8-1 meq/l + placebo

Category

Treatment - Drugs

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

Imam Hossein hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Zahiroddin, Head of the center, professor of psychiatry

Street address

Imam Hossein Hospital, Shahid Madani st

City

Tehran

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical sciences

Full name of responsible person

Rozita Davari-Ashtiani

Position

Assistant professor

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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