Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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 ratin 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
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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