Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the efficacy and side effects of concurrent use of aripiprazole versus placebo with lithium in pediatric patients with acute manic/mixed episodes of bipolar disorder

Protocol summary

Summary

The aim of this randomized, double-blind study is to compare the efficacy and safety of 6-week use of Aripiprazole and lithium combination versus lithium and placebo in manic/mixed episodes of children and adolescent with bipolar disorder (BD). Atotal of forty patients (between 10-17 years-old) with a diagnosis of BD who receive lithium and meet the study criteria will be randomly assigned to either aripiprazole or placebo group. All participants receive lithium (300 mg 3 or 4 times/day). The patients in the intervention group will receive Aripiprazole (2.5 mg for two days, 5mg after that for 2 days, 10mg for two days and 15 mg/day for the rest of the study) and the others in the control group will receive the same doses of placebo. Bipolar severity will be evaluated by using Young Mania Rating Scale (YMRS), Clinical Global Impression Scale (CGIS) and Children's Global Assessment Scale (CGAS). Treatment improvements in manic/mixed episodes of BPD will be assessed after 3 and 6 weeks. Laboratory tests including CBC, FBS, TG, Total Cholesterol, Serum Cr, T4 & TSH will be measured at the baseline and after 6 weeks. Additionally, a side-effect checklist will be filled at the baseline as well as at weeks 3 and 6.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108027202N1**
Registration date: **2011-09-06, 1390/06/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-09-06, 1390/06/15

Registrant information

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

pghaeli@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Reseach of Faculty of Pharmacy of Tehran University of Medical Sciences - Sobhan Darou Co. (for Providing Aripiprazole & Placebo)

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy and side effects of concurrent use of aripiprazole versus placebo with lithium in pediatric patients with acute manic/mixed episodes of bipolar disorder

Public title

Effect of Adding Aripiprazole to Li Therapy in Children & Adolescents with BPD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hospitalized Patients, between 10 to 17 years old, diagnosis of BPD based on DSM-IV-TR
Exclusion criteria: Hypersensitivity to Aripiprazole or Lithium, Severe Medical Conditions (cardiovascular disorders, hepatic, renal and thyroid dysfunctions & severe diabetes), Serious Neurological Disorders, Dehydration, Ketoacidosis, Pregnancy, Lactation, MR patients

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: **40**

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

Ethics committee of Pharmaceutical Sciences Research Center of Tehran University of Medical Sciences

Street address

Faculty of Pharmacy- Tehran University of Medical Sciences-16th Azar Street- Tehran

City

Tehran

Postal code

Approval date

2011-05-17, 1390/02/27

Ethics committee reference number

90-2-27:16-12

Health conditions studied

1

Description of health condition studied

Bipolar Disorder Manic/Mixed phase in Children & Adolescents

ICD-10 code

F30

ICD-10 code description

Manic episode

Primary outcomes

1

Description

efficacy

Timepoint

Baseline, 3 and 6 weeks after the treatment

Method of measurement

Young Mania Rating Scale, CGI-Improvement and CGAS Scales

Secondary outcomes

1

Description

changes in blood glucose level

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

FBS Laboratory test

2

Description

changes in Triglycerides Fasting level

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

TG Laboratory test

3

Description

changes in Total Cholesterol level

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

Total Chol. Laboratory test

4

Description

Blood Cells Counting

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

CBC Laboratory test

5

Description

changes in serum creatinine level

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

Serum Cr. Laboratory test

6

Description

changes in T4, TSH levels

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

Thyroid function test

7

Description

weight changes

Timepoint

Before Entering the Study and 6 Weeks after treatments

Method of measurement

measuring weight by balance

8

Description

other side effects of treatments

Timepoint

after 3 and 6 weeks of treatment

Method of measurement

Side Effect Check List

Intervention groups

1

Description

Intervention group: day 1 to 3: Lithium with usual dose (300mg TDS or QID po) +2.5mg Aripiprazole once daily po - day 3 to 5: Lithium with usual dose (300mg TDS or QID po) + 5mg Aripiprazole once daily po - day 5 to 7: Lithium with usual dose (300mg TDS or QID po) + 10mg Aripiprazole once daily po - day 7 to the end of Study: Lithium with usual dose (300mg TDS or QID po) + 15mg Aripiprazole once daily po - unless dose adjustments required. The patients will receive Lorazepam po PRN or Halopridol Inj PRN if needed.

Category

Treatment - Drugs

2

Description

Control Group: day 1 to 3: Lithium with usual dose (300mg TDS or QID po) + 2.5mg Placebo once daily po - day 3 to 5: Lithium with usual dose (300mg TDS or QID po) + 5mg Placebo once daily po - day 5 to 7: Lithium with usual dose (300mg TDS or QID po) + 10mg Placebo once daily po – day 7 to the end of the study: Lithium with usual dose (300mg TDS or QID po) + 15mg Placebo once daily po -unless dose adjustments required. The patients will receive Lorazepam po PRN or Halopridol Inj PRN if needed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Children & Adolescents Psychiatry of Imam Hussein Hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Department of Children & Adolescents Psychiatry of Rouzbeh Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Reseach of Faculty of Pharmacy

Street address

Faculty of Pharmacy-Tehran University of Medical Sciences-16th Azar Street-Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Sobhan Darou Co.

Full name of responsible person
Dr Farhat

Street address
No. 295- Dr Fatemi Street- Tehran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Sobhan Darou Co.

Proportion provided by this source

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
Faculty of Pharmacy of Tehran University of Medical Scienses

Full name of responsible person
Doctor Padideh Ghaeli

Position
Associate Professor of Clinical Pharmacy,Faculty of Pharmacy of Tehran University of Medical Sciense

Other areas of specialty/work

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Position
Pharm.D Student

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massud.akbari@gmail.com

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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