

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparing changes of biochemical factors in serum of patients with bipolar disorder who received Aripiprazol versus Perfenazin

Protocol summary

Study aim

Comparing the change of biochemical factors in serum of patients with bipolar disorder who receive Aripiprazol and Perfenazin

Design

A randomized clinical trial without control group, with parallel groups, phase 3. without blindness in which 60 patients randomly divided into two groups of 30 subjects using block randomization method and blocks of size 4 and 6.

Settings and conduct

In this study, patients with bipolar disorder who are candidate for antipsychotic drug therapy at Shahid Yahya Nejad Hospital in Babol were randomly divided into two Intervention groups. After 3 month, biochemical factors were checked and compared for all patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No Psychotic symptom; Bipolar disorder diagnosis based on DSM-4-TR; Filling in the personal satisfaction form; Age between 18-50 years.
Exclusion Criteria: Hypertension; High blood lipids; Antihypertensive and antilipid drugs; Diabetes mellitus type-II; Physical disorders; Pregnancy

Intervention groups

Intervention group 1: Tablet Aripiprazole 10 mg (Jalinous Company) with dose range (10-30) and Tablet Sodium Valproate 200 mg (Hakim Company). Intervention group 2: Tablet Perphenazine 8 mg (Darupakhsh Company) with dose range (32-24) And Tablet Sodium Valproate 200 mg (Hakim Company)

Main outcome variables

Biochemical Factors including Fasting Blood Sugar; Triglyceride; Cholesterol; HDL; LDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170606034348N6**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 121 3171

Email address

a.hamidia@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing changes of biochemical factors in serum of patients with bipolar disorder who received Aripiprazol versus Perfenazin

Public title

The effect of Aripiprazol and Perfenazinpatients on

biochemical factors among patients with bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No Psychotic symptom Bipolar disorder diagnosis based on DSM-4-TR Filling in the personal satisfaction form

Ages between 18-50 years

Exclusion criteria:

Hypertension High blood lipids Antihypertensive and antihypertensive drugs Diabetes mellitus type-II Physical disorders Pregnancy

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly divided into two groups of 30 subjects with blocks of size 4 and 6 and an allocation ratio of 1: 1. The participants allocation sequence in two groups was performed with Randomizer software.

Opaque sealed sequentially numbered envelopes used for allocation concealment.

Blinding (investigator's opinion)

Not 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 Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

babol

Province

Mazandaran

Postal code

4713566547

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.278

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Before treatment and three months after treatment

Method of measurement

Laboratory test

2

Description

Triglyceride

Timepoint

Before treatment and three months after treatment

Method of measurement

Laboratory test

3

Description

Cholesterol

Timepoint

Before treatment and three months after treatment

Method of measurement

Laboratory test

4

Description

HDL

Timepoint

Before treatment and three months after treatment

Method of measurement

Laboratory test

5

Description

LDL

Timepoint

Before treatment and three months after treatment

Method of measurement

Laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1:Aripiprazole, 10 mg tablet (produced by Jalinous Company) with dose range of 10-30 and Sodium Valproate 200 mg tablet (produced by Hakim Company) for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group: Perphenazine, 8 mg tablet (produced by Darupakhsh company) and Sodium Valproate, 200 mg tablet (produced by Hakim company) for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Yahya Nejad Hospital

Full name of responsible person

Dr.Azam Ali Akbarian

Street address

Mustafa Khomeini street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

Street address

Vice-chancellor for Research, Daneshgah square,
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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Angela Hamidia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available