Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the Efficacy of Aripiprazole with other Second-Generation Antipsychotics in Acute Mania Symptoms in Manic Patients

Protocol summary

Study aim

Comparing the efficacy of aripiprazole with other second-generation antipsychotics in suppressing acute mania symptoms.

Design

This assessment is a clinical trial in phase 4; patients diagnosed with mania and with acute mania symptoms and confirmed by a psychiatrist are considered as a study group. In this study, 50 patients who have the inclusion criteria, were selected. Patients are classified into two groups by randomization and blocking method, 25 patients in the Aripiprazole group and 25 patients in the second-generation anti psychotic group. Accordingly, at the beginning of the diagnosis, and at 2, 4 and 6 weeks, the status of symptoms of acute Mania is assessed using questionnaires.

Settings and conduct

This study was conducted as a clinical trial in the psychiatric clinic of the Amir Kabir Hospital in Arak. It will also be a one-blind study in which patients will be blinded.

Participants/Inclusion and exclusion criteria

For the purpose of this study, 50 patients with bipolar disorder are required. Patients with bipolar disorder who are referred to Amir Kabir Hospital, aged over 18, are considered as inclusion criteria. The exclusion criteria also include dissatisfaction with participation in the study.

Intervention groups

In the intervention group, treatment with aripiprazole is initiated at baseline dose of 5 to 15 mg per day, after two weeks the dose can be increased to 5 mg, as well as at weeks 4 and 6, this can be 5 mg per day is added to treat them to reach 30 mg per day at the end of 6 weeks. Also in control group, used second-generation anti-psychotic , the drugs used include risperidone, olanzapine, quetiapine and sodium valproate.

Main outcome variables

Symptoms of acute mania

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110819007373N8**
Registration date: **2018-12-29, 1397/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**
Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

Hamidreza Jamilian

Name of organization / entity

Arak University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-05, 1397/09/14

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the Efficacy of Aripiprazole with other Second-Generation Antipsychotics in Acute Mania Symptoms in Manic Patients

Public title
Effectiveness of Aripiprazole in Acute Mania

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with bipolar I disorder in the phase of mania Age older than 18 years Satisfaction for the study

Exclusion criteria:
Patients who have used anti-psychotic medicines for the past 30 days Patients who have been using ECT for the past 6 months Patients who are pregnant or breast-feeding Patients with alcohol dependence Cognitive impairment other than bipolar disorder High risk of suicide The use of medication stabilizers other than sodium valproate liver disorders The history of polycystic ovaries Thrombocytopenia

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomization we will use the block method, Accordingly, the patients under study are divided into two groups. The allocation of patients in two groups was based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients were divided into two equal groups of patients, they enrolled in the study and performed desired intervention on them.

Blinding (investigator's opinion)
Single blinded

Blinding description
This means that patients in groups do not know the used drugs, and drugs has similar packaging.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Basij Square

City
Arak

Province
Markazi

Postal code
3881173533

Approval date
2018-09-22, 1397/06/31

Ethics committee reference number
IR.ARAKMU.REC.1397.149

Health conditions studied

1

Description of health condition studied
Manic

ICD-10 code
F30.1

ICD-10 code description
Manic episode without psychotic symptoms

Primary outcomes

1

Description
Symptoms of acute mania

Timepoint
Initially and 2, 4 and 6 weeks.

Method of measurement
Using Yang Mania Rating Scale (YMRS), Clinical Global Impression Questionnaire (CGI) and Young Mania Rating Scale (YMRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aripiprazole is used in these patients, initiating treatment with aripiprazole at a dose of 5 to 15 mg per day, after two weeks, the dose is increased to 5 mg, also at 4 and 6 weeks it also added 5 mg daily for treatment to reach 30 mg per day at the end of 6 weeks.

Category
Treatment - Drugs

2

Description
Control group: In these patients, second-generation antipsychotic therapy is initiated with risperidone 2-3 mg once daily to a maximum of 6 mg per day, with an increase in the dose not to be greater than 1 mg per day and at intervals Less than 24 hours. Starting treatment with olanzapine is 10-15 mg per day, which can increase to 20-25 mg per day. Initiation of quetiapine treatment is 100 mg daily in divided doses. Increasing to 100 mg daily to 400 mg daily in divided doses on day 4 and on days 5 and 6 daily increases to 200 mg to 800 mg per day. Sodium valproate orally at a dose of 250 mg per day, which can be increased to 250 mg three times a day within 3 to 6 days, ultimately increasing to 1200-1500 mg daily in split doses.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Kabir Hospital

Full name of responsible person
Hamidreza Jamilian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hamidreza Jamilian

Position
Board of Psychiatry,Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be 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
Not applicable

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