

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparing the Efficacy of Aripiprazole with other Second-Generation Antipsychotics in smoke cessation of inpatient Manic sufferers

Protocol summary

Study aim

Comparing the Efficacy of Aripiprazole with other Second-Generation Antipsychotics for smoke cessation

Design

This assessment is a clinical trial. 40 patients diagnosed with mania and with acute mania symptoms and confirmed by a psychiatrist and who have the inclusion criteria will be considered as sample. Patients will be classified into two groups by randomization; 20 patients in the Aripiprazole group and 20 patients in the second-generation anti psychotics other than Aripiprazole group. Accordingly, at the beginning of the diagnosis, and at 2, 4 and 6 weeks, the status of symptoms of nicotine dependency will be assessed using questionnaires.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

over 18 years old inpatient Manic sufferers except those who: used anti-psychotic medicines during the recent past 30 days recieved ECT during the recent past 6 months are pregnant or breast-feeding are alcohol dependent suffer from psychiatric disorders other than bipolar disorder are in high risk for suicide are using mood stabilizers other than sodium valproate suffer from liver disease have a positive history of polycystic ovaries suffer from Thrombocytopenia

Intervention groups

In the intervention group, treatment with Aripiprazole will initiate at baseline dose of 5 to 15 mg per day. After two weeks the dose may increase by 5 mg, as well as at weeks 4 and 6. This can be 5 mg per day to reach maximum 30 mg per day at the end of 6 weeks. Also in control group, second-generation anti-psychotics except Aripiprazole including Risperidone, Olanzapine and Quetiapine will be used.

Main outcome variables

nicotine dependency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181026041468N1**

Registration date: **2019-07-04, 1398/04/13**

Registration timing: **prospective**

Last update: **2019-07-04, 1398/04/13**

Update count: **0**

Registration date

2019-07-04, 1398/04/13

Registrant information

Name

Mehran Shayganfard

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

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 smoke cessation of inpatient Manic sufferers
Public title	Comparing the Efficacy of Aripiprazole with other Second-Generation Antipsychotics in smoke cessation of inpatient Manic sufferers
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Bipolar disorder type-I patients in manic phase older than 18 Informed consent
Exclusion criteria:	Use of anti-psychotic medicines during the recent past 30 days Use of ECT during the recent past 6 months Pregnancy or breast-feeding Alcohol dependence Psychiatric disorders other than bipolar disorder High risk of suicide The use of mood stabilizers other than sodium valproate liver disease Positive 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: 40
Randomization (investigator's opinion)	Randomized
Randomization description	In order to randomization, we will use the block method. Accordingly, the cases will be divided into two groups. The allocation of patients in two groups would be based on demographic characteristics and matching. Therefore, after considering the patients' demographic data, they will be divided into two equal groups of participants. The study will start by performing desired intervention on each group.
Blinding (investigator's opinion)	Single blinded
Blinding description	Patients in either groups are unaware of the used drugs, and drugs has similar package.
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	Alamolhoda
City	Arak
Province	Markazi
Postal code	3881173533
Approval date	2019-02-24, 1397/12/05
Ethics committee reference number	IR.ARAKMU.REC.1397.366
Health conditions studied	
1	
Description of health condition studied	Bipolar mood disorder
ICD-10 code	F34
ICD-10 code description	Persistent mood [affective] disorders
2	
Description of health condition studied	Nicotine dependence
ICD-10 code	F17
ICD-10 code description	Nicotine dependence
Primary outcomes	
1	
Description	nicotine dependence
Timepoint	0, 1, 2, 4, 6 weeks
Method of measurement	Nicotine Dependence Syndrome Scale (NDSS)
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: In the intervention group, treatment

with Aripiprazole will initiate at baseline dose of 5 to 15 mg per day. After two weeks the dose may increase by 5 mg, as well as at weeks 4 and 6. This can be 5 mg per day to reach maximum 30 mg per day at the end of 6 weeks.

Category

Treatment - Drugs

2**Description**

Control group: in control group, second-generation anti-psychotics except Aripiprazole including Risperidone, Olanzapine and Quetiapine will be prescribed.

Category

Treatment - Drugs

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

Amirkabir Hospital, Arak, Iran

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamaly

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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

Mehran Shayganfard

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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

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

Data Dictionary

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