

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 86 3313 5075

##### Email address

mshayganfard@arakmu.ac.ir

##### 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**

Mehran Shayganfard

**Street address**

Alamolhoda

**City**

Arak

**Province**

Markazi

**Postal code**

3818718781

**Phone**

+98 86 3313 5075

**Email**

mshayganfard@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Kamaly

**Street address**

Alamolhoda

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3313 5075

**Email**

mshayganfard@yahoo.com

**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**

Psychiatrics

**Street address**

Alamolhoda

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3313 5075

**Email**

mshayganfard@yahoo.com

**Person responsible for scientific 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**

Psychiatrics

**Street address**

Alamolhoda

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Arak

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**Phone**  
+98 86 3313 5075  
**Email**  
mshayganfard@yahoo.com

## Person responsible for updating data

### 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**  
Psychiatrics  
**Street address**  
Alamolhoda  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**

## 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