

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Clinical trial Comparison of the effect of Aripiprazole and placebo on the rate of smoking in male patients with type I bipolar disorder

#### Protocol summary

##### Summary

Among the patients referred to the clinics and psychiatric clinics of Tabriz 40, men with type bipolar I disorder were selected according to the method of access and according to the criteria for Inclusion and Exclusion, and by blocking method in one of the two intervention or Control groups. After reviewing the case and conducting a structured interview, a definitive diagnosis of bipolar I disorder was made by the psychiatrist and then the necessary explanations were presented morally and, if agreed, were selected as a statistical sample. At first, Fagerstrom Test for Nicotine Dependence was used to determine the rate of smoking in each patient. Then, in the intervention group, Aripiprazole was administered at a dose of 10 mg per day for 6 weeks and placebo control group. During the intervention, patients were not asked to stop their cigarette smoking. After 6 weeks, the rate of smoking in all patients was measured by Fagerstrom Test for Nicotine Dependence. In order to measure the side effects of the drug, a checklist was prepared based on the complications recorded by reviewing the scientific literature and completed on the first and fourth weeks based on interviews with the sample. People who were under the side effects of Aripiprazole were discontinued and excluded, and another was replaced.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016121228173N3**

Registration date: **2017-08-01, 1396/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-01, 1396/05/10

#### Registrant information

##### Name

Salman Safikhanlou

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Email address

safikhanlous@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

#### Expected recruitment start date

2017-01-20, 1395/11/01

#### Expected recruitment end date

2017-04-21, 1396/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Clinical trial Comparison of the effect of Aripiprazole and placebo on the rate of smoking in male patients with type I bipolar disorder

#### Public title

Effect of Aripiprazole on Smoking Rate in Male Bipolar Mood Disorder I

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: The definitive diagnosis of bipolar I disorder according to DSM-IV-TR criteria; being in the partial or complete recovery phase based on Yang Mania

Rating Scale; having the necessary criteria for diagnosis of nicotine dependence according to DSM-IV-TR criteria; age 18-60 Years old; male gender and consent to attend the study through the signing of informed consent.

Exclusion Criteria: history of any allergic reaction to drug disorder with respect to Aripiprazole or other anti psychotics; dependence on other substances (based on the patient's history and the outcome of the test of morphine and methamphetamine at the start of the intervention); the use of other drugs used to quit nicotine; Use of medications other than bipolar disorder; history of physical illness (liver failure, renal failure); history of mental retardation; occurrence of any side effects due to Aripiprazole; history of cognitive impairment (dementia).

#### Age

From **18 years** old to **60 years** old

#### Gender

Male

#### 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

Randomization by blocking method

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street.

##### City

Tabriz

##### Postal code

#### Approval date

2016-12-11, 1395/09/21

#### Ethics committee reference number

IR.TBZMED.REC.1395.922

## Health conditions studied

### 1

#### Description of health condition studied

Bipolar Mood Disorder, current episode manic without psychotic features

#### ICD-10 code

f31.1

#### ICD-10 code description

The patient is currently manic, without psychotic symptoms (as in F30.1), and has had at least one other affective episode (hypomanic, manic, depressive, or mixed) in the past.

## Primary outcomes

### 1

#### Description

Smoking rate (nicotine)

#### Timepoint

before intervention, Six weeks after the intervention

#### Method of measurement

Fagerstrom Test for Nicotine Dependence (FTQ)

## Secondary outcomes

### 1

#### Description

Side effects of Aripiperazole

#### Timepoint

First and Fourth Week of Intervention

#### Method of measurement

Glasgow Antipsychotic Side-effect Scale (GASS)

## Intervention groups

### 1

#### Description

Intervention group: Aripiprazole is administered at a dose of 10 mg per day for 6 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo in terms of shape, size and weight similar to the Aripiprazole drug for 6 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Razi Hospital  
**Full name of responsible person**  
DR Mohammad Taher Taieb Zadegan  
**Street address**  
Razi Hospital, Shahid Bakeri Blvd (El Goli), Tabriz.  
**City**  
Tabriz

## 2

### **Recruitment center**

**Name of recruitment center**  
Clinic  
**Full name of responsible person**  
DR Asghar Arfaie  
**Street address**  
Fifth Floor, Parsa Faculty Building, Between Hajj Jabar  
Nayib and Taleghani, New Pasteur Street, Southern  
Artesh Street, Tabriz.  
**City**  
Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**  
Vice chancellor for research, Tabriz University of  
Medical Sciences  
**Full name of responsible person**  
DR Alireza Shafiee  
**Street address**  
Razi Hospital, Shahid Bakeri Blvd (Elgoli), Tabriz.  
**City**  
Tabriz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Vice chancellor for research, Tabriz University of Medical  
Sciences  
**Proportion provided by this source**  
100  
**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**  
Razi Hospital  
**Full name of responsible person**

DR Mohammad Taher Taieb Zadegan  
**Position**  
resident  
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## **Person responsible for scientific inquiries**

### **Contact**

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Research Center of Psychiatry and Behavioral  
Sciences  
**Full name of responsible person**  
DR Sepideh Herizchi  
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Assistant Professor  
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## **Person responsible for updating data**

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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*