

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

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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

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Research Center of Psychiatry and Behavioral Sciences

Full name of responsible person

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Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

Razi Hospital

Full name of responsible person

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Position

MA of Clinical Psychology

Other areas of specialty/work

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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