# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## A Comparision Between Effect of Aripiprazole and Placebo on the Rate of Nicotine Dependence in Schizophrenic patients

## Protocol summary

**Summary**

The main objective of the project: Assessment of the effect of Aripiprazole on smoking rate in the schizophrenic patients. Study design: a randomized, controlled, before-after, tripple blind clinical trial Study population: 40 patients with schizophrenia will be selected among the patients admitted to the psychiatric clinics of Tabriz by simple (available) method sampling and considering inclusion and exclusion criteria. Then the patients are divided into two groups by respective pairing method. Inclusion criteria : diagnosis of schizophrenia according to DSM IV TR criteria using semi-structured interviews, having necessary criteria for the diagnosis of nicotine dependence criteria according to DSM IV TR Exclusion Criteria: a history of allergy or any side effect due to Aripiprazole or other antipsychotics, dependency to other substances (based on the patient's history and morphine and methamphetamine test results at the time of intervention), use of other drugs used for nicotine withdrawal, active phase of psychosis. First, Using FTQ questionnaire, smoking rates are determined in each patient, then the intervention group will receive a daily dose of 10 mg Aripiprazole for 6 weeks and the control group will receive placebo. During the intervention, the patients are not required to stop smoking. After 6 weeks the smoking rates are measured by FTQ questionair in all patients again. Finally the data are analyzed using the statistical software SPSS 19.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013010512018N1**
Registration date: **2013-04-06, 1392/01/17**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2013-04-06, 1392/01/17

**Registrant information**

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Hossein Javdani
**Name of organization / entity**
Tabriz university of medical sciences
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Clinical Psychiatry Research Center - Tabriz university of medical sciences - Tabriz - Iran

**Expected recruitment start date**

2013-04-21, 1392/02/01

**Expected recruitment end date**

2013-10-23, 1392/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Comparision Between Effect of Aripiprazole and Placebo on the Rate of Nicotine Dependence in Schizophrenic patients

**Public title**

The Effect of Aripiprazole on Smoking Rate in Schizophrenic Patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: diagnosis of schizophrenia according to DSM IV TR criteria using semi-structured interviews,being in partial or complete remission phase, having necessary criteria for the diagnosis of nicotine dependence criteria according to DSM IV TR, aged 18 – 60 years, male sex. exclusion Criteria: a history of allergy or any side effect due to Aripiprazole or other antipsychotics, dependency to other substances (based on the patient's history and morphine and methamphetamine test results at the time of intervention), comorbidity of the other major psychiatric disorders (such as unipolar and bipolar mood disorders), use of other drugs used for nicotine withdrawal, active phase of psychosis.

**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)**

Triple blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Tabriz university of medical sciences

**Street address**

Golgasht street

**City**

Tabriz

**Postal code**

**Approval date**

2013-01-21, 1391/11/02

**Ethics committee reference number**

91197

## Health conditions studied

### 1

**Description of health condition studied**

schizophrenia

**ICD-10 code**

F20

**ICD-10 code description**

The schizophrenic disorders are characterized in general by fundamental and characteristic distortions of thinking and perception, and affects that are inappropriate or blunted. Clear consciousness and intellectual capacity are usually maintained although

## Primary outcomes

### 1

**Description**

the rate of nicotine dependence

**Timepoint**

befor intervention and 6 weeks after intervention

**Method of measurement**

Nicotine Dependence Questionnaire (FAGERSTROM)

## Secondary outcomes

### 1

**Description**

extrapyramidal side effects

**Timepoint**

befor intervention and 6 weeks after intervention

**Method of measurement**

abnormal involuntary movement scale

## Intervention groups

### 1

**Description**

intervention group: tablet Aripiprazole, 10 mg, once daily, for 6 weeks

**Category**

Treatment - Drugs

### 2

**Description**

control group: placebo, one tablet daily, for 6 weeks

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Psychiatric Clinic of Razi Hospital.

**Full name of responsible person**

Hossein Javdani

**Street address**

Ealgoli avenue

**City**

Tabriz

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Clinical Psychiatry Research Center

**Full name of responsible person**

Ali Fakhari

**Street address**

Razi hospital, Ealgoli avenue

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Clinical Psychiatry Research Center

**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**

Tabriz university of medical sciences

**Full name of responsible person**

Asghar Arfaie

**Position**

Associate Professor of psychiatry

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Tabriz university of medical sciences

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Hossein Javdani

**Position**

Assistant of psychiatry

**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*