

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparing the effectiveness of Aripiprazole with other second-generation antipsychotics on smoking dependency in manic patients admitted

Protocol summary

Criteria for "arousal", "priority", "tolerance", "continuity" and "stereotyped behavior" of the NDSS questionnaire

Study aim

Comparison of the effectiveness of aripiprazole with other second-generation antipsychotics in reducing smoking dependence in hospitalized manic patients.

Design

This study was a non-randomized blind clinical trial with parallel groups. After obtaining informed consent, the patients were visited by a psychiatrist and according to their opinion were assigned to one of the two groups for specialized treatment. According to the inclusion and exclusion criteria, 50 patients were included in the study and were evaluated in a 6-week period in two groups of intervention (treated with aripiprazole, n = 25) and control (treated with other second-generation antipsychotics, n = 25) by NDSS questionnaire.

Settings and conduct

Type 1 bipolar patients referred to Amirkabir Hospital in the mania phase according to the opinion of a psychiatrist for treatment with aripiprazole (5 to 15 mg daily) or other second-generation antipsychotics (risperidone 2-3 mg, olanzapine 10-15 mg, quetiapine 100 mg daily) were assigned to one of the two groups. Due to the similarity of drugs, patients were not aware of their group.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Smoker; Age over 18 years; Bipolar I mental disorder hospitalized in the mania phase
Exclusion criteria: Unwillingness to continue; Not allowing the use of information; Use of antipsychotic drugs in the past 30 days; Use of ECT in the last 6 months; Pregnancy or lactation; Alcohol dependence; Mental disorder other than bipolar disorder; High risk of suicide; Use of mood stabilizing drugs other than sodium valproate; Liver disorders; History of polycystic ovaries; Thrombocytopenia

Intervention groups

Smokers with bipolar disorder in mania phase and referred to Amirkabir Hospital in Arak

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201116049406N1**

Registration date: **2020-11-25, 1399/09/05**

Registration timing: **retrospective**

Last update: **2020-11-25, 1399/09/05**

Update count: **0**

Registration date

2020-11-25, 1399/09/05

Registrant information

Name

Sahar Hajihashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3312 3936

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-24, 1397/12/05

Expected recruitment end date

2020-07-26, 1399/05/05

Actual recruitment start date

2020-02-24, 1398/12/05

Actual recruitment end date

2020-07-26, 1399/05/05

Trial completion date

2020-07-26, 1399/05/05

Scientific title

Comparing the effectiveness of Aripiprazole with other second-generation antipsychotics on smoking dependency in manic patients admitted

Public title

effectiveness of Aripiprazole on smoking dependency in manic patients admitted to Amir Kabir Hospital in Arak

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Conscious consent to participate in the study Smokers over 18 years of age with bipolar I psychiatric disorder in phase mania (based on DSM-V)

Exclusion criteria:

All patients who do not want to continue the study and do not consent to participate in the study. Patients who have been taking antipsychotic medications for the past 30 days. Patients who have been treated with ECT for the past 6 months. Pregnancy or lactation, Alcohol dependence, Mental disorder other than bipolar disorder, High risk of suicide, Use of non-loading dose stabilizing drugs other than sodium valproate, Liver disorders, History of polycystic ovary and thrombocytopenia

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Patients participating in the study were unaware of their group.

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

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Arak, Sardasht, Arak University of Medical Sciences, Faculty of Medicine

City

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Province

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Postal code

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Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.ARAKMU.REC1397.366

Health conditions studied**1****Description of health condition studied**

Bipolar type 1 mood disorder

ICD-10 code

F31.1

ICD-10 code description

Bipolar disorder, current episode manic without psychotic features

Primary outcomes**1****Description**

nicotine dependence

Timepoint

0-2-4-6

Method of measurement

NDSS questioner

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Smoking patients with bipolar disorder type 1 receiving aripiprazole

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Amir kabir Hospital

Full name of responsible person

Sahar Hajjhashemi

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Arak, Parstar Square, Amir Kabir Hospital

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Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Position

intern

Latest degree

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Other areas of specialty/work

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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 Kamali

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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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mehran Shaygan far

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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