

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Efficacy of Risperidone vs Aripiprazole in amphetamine induced psychotic disorder

Protocol summary

Summary

According to DSM-IV-TR, Amphetamine induced psychotic disorder occurs within one month after amphetamine withdrawal or intoxication. This disorder is common in amphetamine users and needs to be treated because of severity of symptoms. There is no standard guideline for treatment of this disorder. Risperidone is an atypical antipsychotic which is effective in acute psychosis and has fewer side effects compared to typical antipsychotics. Aripiprazole is a partial D2, 5-HT1A agonist which is effective in acute psychosis and has fewer side effects compared to typical and atypical antipsychotics. We conducted a clinical trial to compare efficacy of Risperidone and Aripiprazole for treatment of this disorder. This is a randomized clinical trial. 38 patients which referred to Kermanshah University of Medical Sciences will be studied in two groups after clinical interview according to our inclusion and exclusion criteria. Patients in group 1 and 2 receive 4 mg Risperidone and 15mg Aripiprazole for 6 weeks respectively. Patients will be assessed by Positive and Negative Syndrome Scale Questionnaire before and after treatment course.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205029620N1**

Registration date: **2012-08-21, 1391/05/31**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2012-08-21, 1391/05/31

Registrant information

Name

Vahid Farnia

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1826 0700

Email address

vfarnia@kums.ac.ir

Recruitment status

Not enough for processing

Funding source

Vice-chancellor for research, Kermanshah university of medical sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Risperidone vs Aripiprazole in amphetamine induced psychotic disorder

Public title

Comparison of Risperidone vs Aripiprazole in amphetamine induced psychotic disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- diagnosis of amphetamine induced psychotic Disorder; 2- Patients agreement for treatment. Exclusion criteria: 1- any history of previous medical & psychiatric disorders; 2- any medication which currently

is used; 3- any substance which currently is used.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 38

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

kermanshah university of medical sciences

Street address

vice-chancellor for research, kermanshah university of medical sciences

City

kermanshah

Postal code**Approval date**

2012-01-31, 1390/11/11

Ethics committee reference number

61021/420/7/پ

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

amphetamines induced psychotic disorder

ICD-10 code

F 15 .15

ICD-10 code description

F 15 .150 - F 15 .151 - F 15 .159

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

Severity of psychotic symptoms

Timepoint

6 Weeks after beginning of treatment course

Method of measurement

PANSS Questionnaire

Secondary outcomes

empty

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

Risperidone 4 mg daily

Category

Treatment - Drugs

2**Description**

aripiprazole 15mg/daily

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farabi educational and treatment center

Full name of responsible person

Vahid Farnia

Street address

Farabi hospital- Isar Blvd

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah university of medical sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice-chancellor for research - Kermanshah university of medical sciences

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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

Kermanshah university of medical sciences

Full name of responsible person

Vahid Farnia

Position

Assistant Professor

Other areas of specialty/work

Street address

Farabi hospital- Isar Blvd

City

Kermanshah

Postal code

Phone

+98 83 1826 0700

Fax

Email

vfarnia@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical sciences

Full name of responsible person

Vahid Farnia

Position

Assistant Professor

Other areas of specialty/work

Street address

Farabi hospital- Isar Blvd

City

Kermanshah

Postal code

Phone

+98 83 1826 0700

Fax

Email

vfarnia@kums.ac.ir

Web page address

Person responsible for updating data

Contact

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