Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Rsperidone and Aripiprazole for treatment of this disorder. This is a randomized clinical trial. 38 patients which refereed 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 Rsperidone 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
amphtamine 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 begining 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

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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