Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effectiveness of aripiprazole and risperidone on the psychotic symptoms of methamphetamine use

Protocol summary

Study aim
Comparing effectiveness of aripiprazole and risperidone in methamphetamine induced psychosis

Design
A block Randomized using a block size of 4, double blinded, two arm parallel group, clinical trial wich is performed on 32 patients in each experimental group.

Settings and conduct
eligible patients Admitted in razi psychiatric hospital diagnosed with Metamphetamin induced psychosis, would be assessed by researcher made questionnaire, vital signs and positive and negative syndrome scale after informed consent and before medication.assessment will be repeated using vital signs and positive and negative syndrome scale 1 week after medication. assessments are going to be repeated again using positive and negative syndrome scale and vital signs and saint Hans rating scale 4weeks after medication. researcher and data gatherer and patients would be unaware of the medication type and physical features of two medication types are going to be similar.

Participants/Inclusion and exclusion criteria
inclusion criteria: informed consent to enter the trial, No other substance dependencies except for Tobacco, diagnosis of Metamphetamin induced psychotic disorder based on Diagnostic and Statistical Manual of Mental Disorders 5th Edition exclusion criteria: major or urgent psychiatric or nonpsychiatric condition including allergies to Risperidone or Aripiprazole, Psychiatric medication use in last 4 weeks other than Benzodiazepines

Intervention groups
intervention group 1:taking Risperidone oral tablet, 2-8mg over 24 hours variable dosage decided by clinical care giver, daily, for at least a month and Abidi pharma brand; intervention group 2:taking Aripiprazole oral tablet, 5-20mg over 24 hours variable dosage decided by clinical care giver, daily, for at least a month and Abidi pharma brand

Main outcome variables
Score of positive and negative syndrom scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220103053615N1**
Registration date: **2022-04-18, 1401/01/29**
Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**
Update count: **0**

Registration date
2022-04-18, 1401/01/29

Registrant information

Name
Sepehr Mazloomi Koohbanani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-30, 1401/02/10

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of aripiprazole and risperidone on the psychotic symptoms of methamphetamine use

Public title
Best Choice between aripiprazole and risperidone in methamphetamine psychosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women with written informed consent to enter the trial At least one Positive and Negative Syndrome Scale score equal or greater than 4 Methamphetamine use in less than 4 weeks leading to admition No other substance dependencies except for Tobacco diagnosis of Metamphetamin induced psychotic disorder according to Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

Exclusion criteria:
Sever nonpsychiatric condition in which Risperidone or Aripiprazole are contraindicated Aripiprazole or Risperidone Allergies Active suicidal or homicidal thoughts Comorbid mood or anxiety disorders Pregnant or nursing women or high suspicion of pregnancy Psychiatric medication use in last 4 weeks other than Benzodiazepines

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
We are going to divide samples into two (A) and (B) groups using block randomization of size 4. letters A and B would be used randomly to make 6 blocks of 4 letters and 6 blocks are going to be labeled with numbers 1 to 6. 16 times, random numbers from 1 to 6 are chosen and corresponding block of letters are written down in a row. For example if the first random number is 2 and second number is 5, letters in block no.2 are written down and letters in block no.5 are going to be written after (repeated up to 16 blocks) and a random row of letters A and B (of size 64) is generated. Number for Place of letters in the row would be written on the sealed envelope and the letters would be placed inside. The envelopes with numbers coresponding to the number of the patients according to participation time, is opened by researcher and group of each participant is determined (A or B) when they roll into the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
this is a double blinded study. Both participants and researcher who is tasked with diagnosis and clinical evaluation, are unaware of the medication given to participants. shape, smell, color and taste of both medications are similar which are delivered by a nurse and researcher is invited by clinical care giver to perform the evaluation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of the University of University of social welfare and rehabilitation sciencess

Street address
University of social welfare and rehabilitation sciencess, Koodakyar st, Daneshjoo blvd, Evin st, Tehran

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Tehran

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Postal code
1985713834

Approval date
2022-03-09, 1400/12/18

Ethics committee reference number
IR.USWR.REC.1400.342

Health conditions studied

1

Description of health condition studied
Metamphetamin induced psychotic disorder

ICD-10 code
F15.15

ICD-10 code description
Other stimulant abuse with stimulant-induced psychotic disorder

Primary outcomes

1

Description

Score of Positive and Negative Syndrome Scale

Timepoint

Days: 0, 7, 28 after medication

Method of measurement

Positive and Negative Syndrome Scale

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1:taking Risperidone oral tablet, 2-8mg over 24 hours variable dosage decided by clinical care giver, daily, for at least a month and abidi pharma brand

Category

Treatment - Drugs

2

Description

intervention group 2:taking Aripiprazole oral tablet, 5-20mg over 24 hours variable dosage decided by clinical care giver, daily, for at least a month and abidi pharma brand

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

Sepehr Mazloomi Koohbanani

Street address

Razi psychiatric hospital, Rastegar Blvd, shahr_e_rey, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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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

University of social welfare and rehabilitation 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

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Sepehr Mazloomi Koohbanani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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