Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Study the efficacy of risperidone compared to placebo plus Electroconvulsive therapy in the treatment of persistent psychosis induced by methamphetamine in patients referred to Farabi hospital of Kermanshah

Protocol summary

Study aim
Study the efficacy of risperidone compared to placebo plus Electroconvulsive therapy in the treatment of persistent psychosis induced by methamphetamine in patients referred to Farabi hospital of Kermanshah

Design
This study is a double-blinded clinical trial. The study population will be included all patients who admitted or outpatient with psychosis associated with taking methamphetamine in Farabi hospital of Kermanshah city.12 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct
This study which will be conducted in Farabi hospital of Kermanshah city is double-blinded. At the baseline, the severity of psychosis symptoms will be recorded based on the questionnaire. Then, in the second and fourth weeks, the questionnaire will be returned to the patients and the two groups will be compared in the term of psychosis symptoms severity.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the presence of psychosis due to methamphetamine consumption despite discontinuation of methamphetamine for one month; no history of previous psychiatric disorders such as schizophrenia. Exclusion criteria: the presence of recent cardiovascular disease based on the patient's history or cardiologist's opinion; no medical diseases that have psychosis symptoms such as brain tumors and ...; recent cerebrovascular diseases based on the patient's history or neurologists opinion; sensitivity or complications during treatment with risperidone.

Intervention groups
The first intervention group will receive 4 mg Risperidone (in two divided doses) daily for 4 weeks with a two-way frontotemporal ECT. The second intervention group will receive placebo and ECT as two-way frontotemporal twice a week for 4 weeks (Risperidone and placebo will be provided in 30pcs-drug containers).

Main outcome variables
Severity of psychotic symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N101**
Registration date: **2018-09-18, 1397/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**
Update count: **0**

Registration date
2018-09-18, 1397/06/27

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2018-09-18, 1397/06/27

Expected recruitment end date

2018-10-19, 1397/07/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the efficacy of risperidone compared to placebo plus Electroconvulsive therapy in the treatment of persistent psychosis induced by methamphetamine in patients referred to Farabi hospital of Kermanshah

Public title

Study the efficacy of risperidone in the treatment of persistent psychosis induced by methamphetamine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of psychosis due to methamphetamine consumption despite discontinuation of methamphetamine for one month No history of previous psychiatric disorders such as schizophrenia and ..... No medical diseases that have psychosis symptoms such as brain tumors and ...

Exclusion criteria:

No persistent psychosis associated with methamphetamine abuse. The presence of recent cardiovascular disease based on the patient's history or cardiologist's opinion Sensitivity or side effects during treatment with risperidone. History or presence of primary psychosis

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly by coin toss

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and researcher will be blinded to the study groups, the dosage of the drug and the manufacturer of the drug

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2017-10-26, 1396/08/04

Ethics committee reference number

IR.KUMS.REC.1396.396

Health conditions studied

1

Description of health condition studied

Amphtamine induced psychotic disorder

ICD-10 code

F 15

ICD-10 code description

Mental and behavioural disorders due to use of other stimulants, including caffeine

Primary outcomes

1

Description

Severity of psychotic symptoms

Timepoint

At the beginning of the study, the second week and at the end of the study (4 weeks after the start of the study)

Method of measurement

Based on the Positive and Negative Symptoms Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive 4 mg Risperidone (in two divided doses) daily for 4 weeks with a two-way frontotemporal ECT.
Category
Treatment - Drugs

2

Description
The second intervention group will receive placebo and ECT as two-way frontotemporal twice a week for 4 weeks (Risperidone and placebo will be provided in 30pcs-drug containers)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Abdoll Reza Darki
Street address
Farabi Hospital, Isar Square, Dolatabad Blvd,
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darki121@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
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+98 83 3836 0014
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fnajafi@kums.ac.ir
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
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
Kermanshah University of Medical Sciences
Full name of responsible person
Abdoll Reza Darki
Position
Resident of psychiatrist
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact
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Position
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Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
4 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail
Comments