

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

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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

Amphetamine 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

Abdollah Reza Darki

Street address

Farabi Hospital, Isar Square, Dolatabad Blvd,

City

Kermanshah

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Postal code

6715847141

Phone

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Email

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

Street address

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

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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

Abdollah Reza Darki

Position

Resident of psychiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Farabi Hospital Isar Square, Dolatabad Blvd,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Vahid Farnia

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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

Kermanshah University of Medical Sciences

Full name of responsible person

Abdollah Reza Darki

Position

Resident of psychiatrist

Latest degree

Medical doctor

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Phone

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Fax**Email**

darki121@yahoo.com

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