Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Metamphetamine associated psychosis treatment with haloperidol versus rispridone: a clinical trial

Protocol summary

Summary

The aim of the study is comparing haloperidol with risperidone in the treatment of positive symptoms of psychosis among methamphetamine dependent patients (Phase II clinical trials). The population of this non blinded study is the inpatients of Razi psychiatric hospital in Tehran who met DSM.IV-TR criteria for methamphetamine-associated psychosis (MAP). 44 patients, who had the inclusion criteria, were randomly selected. Inclusion criteria: Patient between 18 to 60 Years; signing informed consent. Exclusion criteria: presence of other psychiatric disorders; abusing of other psycho stimulant drugs; comorbidity of neurological disorders; mental retardation. The subjects were randomly (simple random sampling using random number table) assigned to treatment groups (rispridone or haloperidol). Group 1, 22 patients received Haloperidol (5 to 20 mg, per day) and group 2, 22 patients received Risperidone (2 to 8 mg, per day) for 3 consecutive weeks. Patients were followed one week after interventions. The primary outcome was positive symptoms of psychosis. The Scale for the Assessment of Positive Symptoms (SAPS) was weekly completed for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507155280N19**
Registration date: **2016-01-15, 1394/10/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-15, 1394/10/25

Registrant information

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Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2012-08-31, 1391/06/10

Expected recruitment end date

2013-02-28, 1391/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Metamphetamine associated psychosis treatment with haloperidol versus rispridone: a clinical trial

Public title

Methamphetamine associated psychosis and treatment with risperidone and halopridol

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient in the age range 18 to 60; signing informed consent. Exclusion criteria: presence of

other psychiatric disorders; abusing of other psycho stimulant drugs; comorbid neurological disorders; mental retardation.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Simple random sampling using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Zip code: 1985713834, University of Social Welfare and Rehabilitation Sciences, Koodakyar Street, Daneshjoo Blv, Evin, Tehran, Iran, Islamic Republic Of

City

Tehran

Postal code

Approval date

2012-09-23, 1391/07/02

Ethics committee reference number

REC.1392.111

Health conditions studied

1

Description of health condition studied

Methamphetamine-associated psychosis

ICD-10 code

F15

ICD-10 code description

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

Primary outcomes

1

Description

Methamphetamine-associated psychosis

Timepoint

Baseline, the first week after intervention, the second week after intervention, the third week after intervention, the first week after finishing the intervention

Method of measurement

Scale of Assessment of Positive Symptoms (SAPS)

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 received Haloperidol (5 to 20 mg, per day) for 3 weeks.

Category

Treatment - Drugs

2

Description

Group 2 received Risperidone (2 to 8 mg, per day) for 3 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

Dr Reza Daneshmand

Street address

Zip code: 1985713834, University of Social Welfare and Rehabilitation Sciences, Koodakyar Street, Daneshjoo Blv, Evin, Tehran, Iran, Islamic Republic Of

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Hamid Reza Khankeh

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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
Vice chancellor for research of University of Social Welfare and Rehabilitation 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
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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