

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Effect of Risperidone on reducing the symptoms of methamphetamine induced psychosis

#### Protocol summary

##### Summary

(1) Objectives: our aim in this study is to evaluate the effects of Risperidone on reducing the symptoms of methamphetamine induced psychosis. (2) Design: In an intervention study with before and after design, 32 patients with methamphetamine induced psychosis from both genders will be selected from addiction treatment ward after qualifying the inclusion and exclusion criteria and obtaining the informed consent. (3) Setting and conduct: After a positive urine amphetamine test and diagnosis of psychotic disorder due to methamphetamine use which is going to be confirmed by a psychiatrist, SANS (for negative symptoms) and SAPS (for positive symptoms) scales will be performed. Risperidone will be administered based on therapeutic dose after scoring and determining the severity of symptoms. After one week, SANS and SAPS scales are going to be performed again and results will be compared. Exclusion criteria will be patient's unwillingness to continue to participate in the study. (4) Interventions: after clinical interview and scaling of SANS and SAPS, Risperidone will be administered by the severity of symptoms. (5) Main outcome measures: SAPS scale for measuring positive symptoms of psychosis and SANS scale for measuring negative symptoms of psychosis, then these scales will be compared one week after administration of Risperidone.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311199858N5**  
Registration date: **2013-11-30, 1392/09/09**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-11-30, 1392/09/09

##### Registrant information

###### Name

Arash Mohagheghi

###### Name of organization / entity

Clinical Psychiatry Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 3353098411380

###### Email address

mohagheghia@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-12-01, 1392/09/10

##### Expected recruitment end date

2014-05-31, 1393/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Risperidone on reducing the symptoms of methamphetamine induced psychosis

##### Public title

Effect of Risperidone on psychosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. At least 18 years of age 2. Diagnosis

of methamphetamine induced psychosis with structured clinical interview SCID by the approval of a psychiatrist or a psychologist. 3. No anti-psychotic drug use. 4. No other psychological disorders. Exclusion criteria: Patient's unwillingness to continue to participate in the study.

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **32**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Street address

Vice Chancellor for Research, tabriz University of Medical Sciences, Daneshgah street, tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2013-11-18, 1392/08/27

#### Ethics committee reference number

5/4/6905

## Health conditions studied

### 1

#### Description of health condition studied

سایکوز ناشی از مصرف مواد

#### ICD-10 code

F15.5

#### ICD-10 code description

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

## Primary outcomes

### 1

#### Description

Negative symptoms of psychosis

#### Timepoint

before intervention and 1 week after intervention

#### Method of measurement

Scale for the Assessment of negative Symptoms (SANS)

### 2

#### Description

Positive symptoms of psychosis

#### Timepoint

before intervention and 1 week after intervention

#### Method of measurement

Scale for the Assessment of Positive Symptoms (SAPS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

After determining the severity of symptoms and scoring by the physician, Tablet Risperidone 1 mg daily with therapeutic dosage of 1 to 3 mg daily will be administered for 1 week.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Dr. Arash Mohagheghi

##### Street address

Razi Hospital, El Goli Road, Tabriz, Iran

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Seyyed Kazem Shakouri

##### Street address

Vice chancellor for research, Tabriz University of

Medical Sciences, Daneshgah street, Tabriz

**City**

Tabriz

**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, Tabriz 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**

Clinical Psychiatry Research Center

**Full name of responsible person**

Dr. Arash Mohagheghi

**Position**

Associate professor of psychiatry

**Other areas of specialty/work**

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**Web page address**

**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*