

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Efficacy of Clozapine in Patients with Prolonged Methamphetamine Induced Psychotic Disorder: A Single-blind Comparison With Olanzapine in drug abusers**

#### **Protocol summary**

##### **Summary**

1- Objectives: Study the effectiveness of Clozapine in the treatment of prolonged Methamphetamine induced psychotic disorder in substance abuser in addiction treatment centers covered by Iran University of Medical Sciences in Tehran in the first half of 1395 in Tehran who have a history of using drugs. 2- Design: This study is a single-blind clinical trial is to evaluate the efficacy of Clozapine in the treatment of prolonged Methamphetamine induced psychotic disorder in substance abuser referred to addiction treatment centers covered by the University of Medical Sciences in the first half of 1395 in Tehran, who have a history of using drugs and psychiatric diagnosis criteria based on DSM 5 with psychotic disorders caused by Methamphetamine use have been diagnosed (both inpatient and outpatient) setting criteria for psychosis, which lasted 8 weeks of treatment with adequate doses provided to ensure drug compliance (MPR higher than 80) will be designed. 3- Setting and Conduct: Patients will be randomly divided into two groups so that a group Clozapine and other group Olanzapine will receive. Before the start of treatment and as a base or zero-day study, all the patients in terms of symptoms and psychosis severity by questionnaire PANSS, the extrapyramidal side effects on the basis of a scale of extrapyramidal side effects (ESRS) and the Craving on the basis of Craving Beliefs Questionnaire (CBQ) will be evaluated and then follow-up of patients at baseline, the end of the fourth week and eighth week will end. 4- Participants including major eligibility criteria: Inclusion criteria: 1- A psychotic disorder caused by prolonged use of methamphetamine (more than 1 month psychotic and at the same time cocaine has not); 2- obtaining the informed consent of the patient's guardian; 3- The absence of mental retardation (moderate or severe); 4- Non-organic neurological disease leading to clinical standpoint.

Exclusion criteria: 1- If the loss of white blood cells or neutrophils less than 3,000 is less than 1,500; 2- Unwillingness to continue to participate in the study. 5- Intervention: In the first stage of a medical and drug history the patient will be taken and then medical examination will be done. Trial-by CBC and ECG at baseline for all patients will be performed. For the group treated with Clozapine, based on the standard of care protocol venous blood sampling blood cell count every week until the end of the six week study and measurement of liver enzymes is done with and for the group treated with Olanzapine retesting of intravenous blood samples After six weeks treatment in Start study done to assess liver enzymes. Patients will be selected by convenience sampling method and randomly divided into two groups of 20 by minimizing a group treated with clozapine and olanzapine will be the second group. Randomly listed by age and baseline PANSS score psychosis is in this way that the first 3 patients in the study are randomly placed in two groups and then the new person on the basis of age and score. 6- Main outcome measures: Before the start of treatment and as a base or zero-day study, all the patients in terms of psychosis symptoms by questionnaire PANSS, the extrapyramidal side effects on the basis of a scale of extrapyramidal side effects (ESRS) and the Craving on the basis of Craving Beliefs Questionnaire (CBQ) will be evaluated and then follow-up of patients at baseline, the end of the fourth week and eighth week will end. In addition to the above-mentioned questionnaire, a demographic questionnaire made by the researcher, including age, sex, education, duration of abuse, the age of onset of drug use, the type of substance, other drug use, age at onset of psychotic symptoms at their disposal to complete by patients.

#### **General information**

##### **Acronym**

## IRCT registration information

IRCT registration number: **IRCT2015112225191N1**

Registration date: **2016-01-17, 1394/10/27**

Registration timing: **prospective**

Last update:

Update count: **0**

## Registration date

2016-01-17, 1394/10/27

## Registrant information

### Name

Behnam Shariati

### Name of organization / entity

### Country

Iran (Islamic Republic of)

### Phone

+98 21 6435 2331

### Email address

shariati.b@iums.ac.ir

## Recruitment status

**Recruitment complete**

## Funding source

Iran University of Medical Sciences Vice chancellor for research

## Expected recruitment start date

2016-04-04, 1395/01/16

## Expected recruitment end date

2017-04-05, 1396/01/16

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Efficacy of Clozapine in Patients with Prolonged Methamphetamine Induced Psychotic Disorder: A Single-blind Comparison With Olanzapine in drug abusers

## Public title

Efficacy of Clozapine in Patients with Prolonged Methamphetamine Induced Psychotic Disorder: A Single-blind Comparison With Olanzapine

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1- A psychotic disorder caused by prolonged use of methamphetamine (more than 1 month psychotic and at the same time cocaine has not); 2- obtaining the informed consent of the patient's guardian; 3- The absence of mental retardation (moderate or severe); 4- Non-organic neurological disease leading to clinical standpoint. Exclusion criteria: 1- If the loss of white blood cells or neutrophils less than 3,000 is less than 1,500; 2- Unwillingness to continue to participate in the study.

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

none

#### Secondary trial Id

none

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mental Health Research Center, Iran University of Medical Sciences Ethics Committee

##### Street address

School of Behavioral Sciences and Health psycho  
Tehran Psychiatric Institute, Niayesh street, Sattar  
Khan Street, Tehran

##### City

Tehran

##### Postal code

1445613111

#### Approval date

2015-09-23, 1394/07/01

#### Ethics committee reference number

2040920409

## Health conditions studied

### 1

#### Description of health condition studied

Resistant Psychosis Induced by Methamphetamine

#### ICD-10 code

F15

#### ICD-10 code description

This block contains a wide variety of disorders that differ

in severity and clinical form but that are all related to the use of one or more drugs, which may or may not prescribe medicine. The third letter of the code identify the materials involved, and

## Primary outcomes

### 1

#### Description

The severity of Symptoms and Psychosis Protests

#### Timepoint

Baseline, the end of the fourth week and eighth week

#### Method of measurement

Based on the PANSS Scale

### 2

#### Description

Craving

#### Timepoint

At baseline, the end of the fourth week and eighth week

#### Method of measurement

Craving Beliefs Questionnaire (CBQ)

## Secondary outcomes

### 1

#### Description

Extrapyramidal Side Effects

#### Timepoint

Baseline, the end of the fourth week and eighth week

#### Method of measurement

Scale Extrapyramidal Side Effects ((ESRs)

## Intervention groups

### 1

#### Description

In the first stage of a medical history and medical examination will be done and then the patient will be taken. Complete blood count tests Valktrvkardiyvgram or ECG at baseline for all patients will be performed. For the group treated with clozapine, based on the standard of care protocol venous blood sampling blood cell count every week until the end of the six week study and measurement of liver enzymes is done with and for the group treated with olanzapine retesting of blood samples After six weeks of intravenous treatment Sharveh study done to assess liver enzymes. Patients will be selected by convenience sampling method and randomly divided into two groups of 20 by minimizing a group treated with clozapine and olanzapine will be the second group. In addition to the above-mentioned questionnaire, a demographic questionnaire made by the researcher, including age, sex, education, duration of abuse, the age of onset of drug use, the type of substance, other drug use, age at onset of psychotic symptoms at their disposal to complete will be placed. Clozapine treatment dose of 6.25 mg up to 450 mg on the first day and will continue

#### Category

Treatment - Drugs

### 2

#### Description

In the first stage of a medical history and medical examination will be done and then the patient will be taken. CBC tests Valktrvkardiyvgram or ECG at baseline for all patients will be performed. For the group treated with olanzapine retesting of blood samples after treatment Sharveh six week study done to assess liver enzymes. Olanzapine dose of 5 mg to 15 mg on the first day and will continue

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iran Hospital MMT

##### Full name of responsible person

Elham Farahani

##### Street address

Iran Psychiatric Hospital, 7 km road in Karaj

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences Vice chancellor for research

##### Full name of responsible person

Dr Behnam Shariati

##### Street address

Highway martyr Hemmat, Tehran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran University of Medical Sciences Vice chancellor for research

#### 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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Behnam Shariati

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

Elmira Ariana Kia

**Position**

Master of Clinical Psychology

**Other areas of specialty/work**

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Number 13 & 15, Counseling Center of Tehran  
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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*