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 Valktrvkardyvgram 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 Valktrvkardyvgram 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
Rasool Hospital, St. Mansouri,, St.Niayesh, Starkhan,Tehran
City
Tehran
Postal code
Phone
+98 21 6435 2331
Fax
Email
behnamshariatimd@gmail.com
Web page address

Person responsible for scientific 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
School of Behavioral Sciences and Health psycho Tehran Psychiatric Institute, Niayesh street,Sattar Khan Street, Tehran
City
Tehran
Postal code
Phone
+98 21 6435 2331
Fax
Email
.
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Counseling Center of Tehran University
Full name of responsible person
Elmira Ariana Kia
Position
Master of Clinical Psychology
Other areas of specialty/work
Street address
Number 13 & 15, Counseling Center of Tehran University, St. Edward Brown, North Kargar St., Enghelab Square.
City
Tehran
Postal code
Phone
Fax
Email
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