Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of different doses of buprenorphine (8mg, 2mg) on the reduction of methamphetamine withdrawal symptoms, depression, suicidal thought and anxiety.

Protocol summary

Summary
The aim of this trial is to compare the effect of buprenorphine (8mg, 2mg) in reduction of methamphetamine craving, depression, suicidal thought and anxiety. In this double blind trial at least 66 inpatients will be selected and by random sampling will be divided to three groups and each group includes at least 22 patients. Each group receives buprenorphine 8 mg or 2 mg or placebo for a period of at least five days. We evaluate the craving of patients by interview and questionnaire every day to find more effective medication. Inclusion criteria: Age between 18 to 60; They are free to participate in the study; Patient's major substance use be methamphetamine. Exclusion criteria: Patients unwilling to participate at beginning or during the study; Use of another substance except Methamphetamine as of the main substance.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2017081525160N8**
Registration date: **2017-08-25, 1396/06/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2017-08-25, 1396/06/03

Registrant information
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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2017-08-15, 1396/05/24
Expected recruitment end date
2018-10-16, 1397/07/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of different doses of buprenorphine (8mg, 2mg) on the reduction of methamphetamine withdrawal symptoms, depression, suicidal thought and anxiety.

Public title
Comparison of the efficacy of different doses of buprenorphine (8mg, 2mg) on the reduction of methamphetamine(crystal, Shishe) withdrawal symptoms, depression, suicidal thought and anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age: 18-60 ;informed consent; methamphetamine dependence Exclusion criteria:Patients unwilling to participate at beginning or during the study; use of another substance except

Methamphetamine as of the main substance.

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

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand blvd

City
Shiraz

Postal code
7194634786

Approval date
2017-08-01, 1396/05/10

Ethics committee reference number
IR.SUMS.REC

Health conditions studied

1

Description of health condition studied
Methamphetamine Dependency

ICD-10 code
F15

ICD-10 code description
Mental and behavioural disorders due to use of other stimulants, including caffeine

Primary outcomes

1

Description
Craving, depression, suicidal thoughts and anxiety

Timepoint
Daily for 5 days

Method of measurement
Questionnaire and interview

Secondary outcomes

empty

Intervention groups

1

Description
We will use buprenorphine 8mg sublingual daily for one group for at least 5 days

Category
Treatment - Drugs

2

Description
We will use buprenorphine 2 mg sublingual daily for the other group at least 5 days.

Category
Treatment - Drugs

3

Description
We will use placebo sublingual daily for one group for at least 5 days

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
EbneSina Hospital

Full name of responsible person
Jamshid Ahmadi M.D

Street address
EbneSina Hospital, Hafeziye street

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
SeyedBasirHashemi

Street address
vice Chancellery for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

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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