Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Efficacy of Adding Buprenorphine with Placebo in Reducing Craving in Methamphetamine Dependent Patients during Treatment with Matrix Model

Protocol summary

Summary

We investigated the efficacy of adding Buprenorphine or placebo in reducing the usage tendency in methamphetamine-depended patients during treatment with Matrix program. Inclusion criteria include men and women age 18–40 years old who were diagnosed with methamphetamine dependency according to DSM-IV criteria and exclusion criteria include a current neurological or axis I psychiatric disorders not due to substance abuse that would impair ability to participate safely in the study and subjects who met DSM-IV criteria for opiates dependence. The 40 subjects were selected from patients who referred to Addiction Treatment Center of Isfahan Noor hospital to attend meetings of matrix program during 2012 to 2013. After screening the subjects were participated in matrix program and randomly were divided into two groups of Buprenorphine and placebo. A 4-months program of intervention was arranged for each group and they were visited by a psychiatrist every two weeks. Buprenorphine began at a dose of 2 mg per day and increased to 6 mg within 7 days (3 sublingual tablets) and this amount continued for 4 months. The craving was assessed by Cocaine Craving Questionnaire-Brief (CCQ-Brief) at screening and every 2 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406017841N6**
Registration date: **2014-06-06, 1393/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-06, 1393/03/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Behavioral Sciences Research Center

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-10-01, 1392/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Efficacy of Adding Buprenorphine with Placebo in Reducing Craving in Methamphetamine Dependent Patients during Treatment with Matrix Model

Public title

Comparing of Buprenorphine with Placebo in Reducing Methamphetamine Craving

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: men and women age 18–40 years old; diagnosed with methamphetamin dependency according to DSM-IV criteria; informed acceptance to comply with study procedures. Exclusion criteria: sever medical illness that would impair the ability to participate safely in the study; a current neurological or axis I psychiatric disorders not due to substance abuse (e.g., schizophrenia, dementia) that would impair ability to participate safely in the study; current pregnancy or nursing in women; current serious suicidal intention or plan; more than 3 times elevation of AST and ALT at screening; subjects who met DSM-IV criteria for opiates dependence.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
Isfahan University of Medical Sciences
Street address
Hezar jerib Street
City
Isfahan
Postal code
Approval date
2011-12-17, 1390/09/26
Ethics committee reference number
8/3127/د

Health conditions studied

1

Description of health condition studied
Methamphetamine Dependency
ICD-10 code
F15.2
ICD-10 code description
Mental and behavioural disorders due to use of other stimulants, including caffeine.Dependence syndrome

Primary outcomes

1

Description
Methamphetamine Craving
Timepoint
At screening and every 2 weeks up to 4 months
Method of measurement
Cocaine Craving Questionnaire-Brief (CCQ-Brief)

Secondary outcomes

1

Description
Vomiting
Timepoint
At screening and every 2 weeks up to 4 months
Method of measurement
History and Physical examination

2

Description
Dyspepsia
Timepoint
At screening and every 2 weeks up to 4 months
Method of measurement
History and Physical examination

3

Description
Drowsiness
Timepoint
At screening and every 2 weeks up to 4 months
Method of measurement
History and Physical examination

Intervention groups

1

Description
Intervention group: Buprenorphine sublingual tab began at a dose of 2 mg per day and increased to 6 mg within 7 days (3 sublingual tablets) and this amount continued for 4 months.
Category
Treatment - Drugs

2

Description
Control group: A placebo with similar medicinal form to buprenorphine which is in sublingual form, began and continued for 4 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric Drug Treatment Center, Emergency and Clinic of Noor Hospital
Full name of responsible person
Ali Reza Emadossadati
Street address
Ostandari street, Noor Hospital
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, Behavioral Sciences Research Center
Full name of responsible person
Dr Abas Atari
Street address
Ostandari Street, Noor Hospital
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, Behavioral Sciences Research Center
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
Isfahan University of Medical Sciences, Department of Psychiatry
Full name of responsible person
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Person responsible for updating data

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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