Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Efficacy of add on buprenorphine vs. placebo on reduction of relapse among people with Met Amphetamine dependency during Matrix program

Protocol summary

Study aim
Effect of Buprenorphine Addition to Matrix Therapy Compared to Placebo on Prevention of Recurrence of methamphetamine use.

Design
This study is a double-blind randomized controlled clinical trial

Settings and conduct
The study sample will be peoples afflicted with methamphetamine use disorder (based on DSM-V criteria) who will be referred to outpatient clinic of addiction Treatment Center of khorshid hospital in Isfahan for participating in "Matrix treatment program". Individuals will be screened for inclusion criteria using clinical psychiatric interview and physical examination. Oral explanation will be represent about the design, purpose, duration of the study, types of medications and probable risks and then a written informed consent form will be completed by participants. participants will be randomly assigned to either the buprenorphine or placebo groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) ages of 18-60 years 2) Having the DSM-V criteria for methamphetamine use disorder 3) It is dependent only on methamphetamine 4) No pregnancy and lactation Exclusion criteria: 1) Any psychiatric disorder that require hospitalization 2) unstable medical condition. 3) Any drug side effects that the person does not tolerate continued medication use.

Intervention groups
For the intervention group, buprenorphine will be started in a sublingual form at 2mg daily and increased to 4mg / day (2 sublingual tablets) over a 7-day period and continued for 1 month and then gradually discontinue within 2 weeks. In the control group, placebo is administered to patients with a similar drug form of buprenorphine (to be provided sublingual by the Faculty of Pharmacy) and lasts up to 1 month and then gradually discontinue within 2 weeks..

Main outcome variables
Reduction of relapse in methamphetamine-dependent patients following the use of buprenorphine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090801002266N12**
Registration date: **2020-03-17, 1398/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-17, 1398/12/27**
Update count: **0**

Registration date
2020-03-17, 1398/12/27

Registrant information

Name
Gholamreza Kheirabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 1222 2135

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of add on buprenorphine vs. placebo on reduction of relapse among people with Met Amphetamine dependency during Matrix program

Public title

buprenorphine efficacy in methamphetamin dependency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) People 18-60 years old 2)Having the DSM-V criteria for methamphetamine use disorder 3) It is dependent only on methamphetamine 4) No pregnancy and lactation

Exclusion criteria:

1)Any psychiatric disorder that require hospitalization 2) Medical condition that interfere with participating in the study 3)Any side effect that interfere with continuation of buprenorphin

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Given the sample size of 40 people, Sampling will be done in ten blocks of four, In each block, two individuals will be randomly assigned to the intervention group and two to the control group, so that all six states of a four-block may be selected ten times randomly from the six blocks. By the end, twenty people in each group will be randomly assigned blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the study did not know whether they would take the drug placebo. Principal investigators are also blinded to this, and the drug and placebo are provided in code-packs by the person who is not directly involved in the study. People who are evaluating and recording the study outcomes are also unaware that the patient has received the drug or the placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

etic commeettee of Isfahan University of Medical Sciences

Street address

vicechancelor for research , Isfahan University of Medical Sciences, Hezarjerib St. Isfahan Iran

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Isfahan

Province

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Postal code

81746-73461

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.MUI.MED.REC.1398.243

Health conditions studied

1

Description of health condition studied

Methamphetamine use disorder

ICD-10 code

F10-F19

ICD-10 code description

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

Primary outcomes

1

Description

substance use craving

Timepoint

weeks 1-8 and 12,16,20,and 24

Method of measurement

questionair

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: buprenorphine In the intervention group, buprenorphine will be started in a sublingual form (made by Mehr Pharmaceutical Company) at a dose of 2 mg daily and increased to 4 mg daily (2 sublingual

tablets) over a 7-day period and continued for 1 month. And then gradually discontinue within 2 weeks. Patients will be evaluated by urine methamphetamine test and CCQ-Brief questionnaire at the time of each week during intervention and after the 1 month in follow-up period

Category

Treatment - Drugs

2

Description

Control group: placebo In the control group, placebo with the same form as buprenorphine (prepared by the Faculty of Pharmacy) would be used in sublingual and with a similar protocol to the intervention group for up to 1 month. and similar to the intervention group they would be assessed with a urine amphetamine test and a CCQ-Brief questionnaire weekly at the time of intervention and monthly during the follow-up period

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital- هسبشاشد

Full name of responsible person

Gholamreza Kheirabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfarayen University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfarayen University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Kheirabadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there are no more data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available