Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of adding perphenazine to Matrix intervention on control of craving and relapse in methamphetamine users

Protocol summary

Study aim
The effect of adding perphenazine to matrix treatment program on the craving and relapse in methamphetamine users compared with placebo

Design
This study is a double-blind randomized controlled clinical trial. Individuals will be screened for inclusion criteria using clinical psychiatric interview and physical examination. All participants will complete a written informed consent form . All participants will be randomly assigned to the perphenazine and placebo groups after randomization. Both groups will be treated with a 2-month Matrix program and then followed up for a 4-month period.

Settings and conduct
participants will include those who will be referred to the Isfahan Welfare Organization for treatment by participating in the Matrix Therapy Program with a diagnosis of methamphetamine use disorder.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Having DSM-V-based methamphetamine dependency criteria 2- Not using other other substances at the same time 3- Not using other psychiatric drugs at the same time Exclusion criteria: 1-Not wanting to continue cooperation for any reason 2- Psychiatric p

Intervention groups
In the intervention group, perphenazine starts at 8 mg / day and then, if the craving to methamphetamine persists, increases 8 mg / week to reach the final dose of 32 mg / day and continued until the end of the intervention. The placebo in control group prescribes and continues with the same drug form and same protocol as perphenazine.

Main outcome variables
Assessment of craving for and return to methamphetamine use

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090801002266N13**
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)

Phone
+98 31 1222 2135

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kheirabadi@bsrc.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of adding perphenazine to Matrix intervention on control of craving and relapse in methamphetamine users

Public title
The effect of perphenazine on methamphetamine dependence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Methamphetamine use disorder criteria based on DSM5 Ages 18 to 50 years Dependence only on methamphetamine Non-pregnancy and lactation Lack of psychosis or severe mood disorder requiring hospitalization Non-simultaneous use of other substances Non-simultaneous use of psychiatric medicines
Exclusion criteria:
Unwillingness to continue collaborating during the study Psychiatric problems requiring hospitalization during the study
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be selected by available sampling method based on inclusion and exclusion criteria and will be randomly assigned to one of two intervention or control groups after obtaining written consent.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will not be aware of the type of drug they are taking, and the drugs will be given in separate packages, and the shape and color of the drugs and the placebo will not be identifiable. Individuals who perform the intervention process and control the recovery process will also not be aware of the allocation of patients to the intervention and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of esfahan University of Medical Sciences
Street address
vicechancelor for research , Isfahan University of Medical Sciences, Hezarjerib St. Isfahan Iran
City
esfahan
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Isfehan
Postal code
81746-73461
Approval date
2019-08-26, 1398/06/04
Ethics committee reference number
ir.mui.med.rec.1398.228

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: In the intervention group, buprenorphine will be started in a sublingual form (made by Mehr Pharmaceutical Company) at 2 mg daily and increase to 4 mg / day (2 sublingual tablets) over a 7-day period and Continue for 1 month and then gradually discontinue within 2 weeks.
Category
Treatment - Drugs

2

Description
Control group: In control group, placebo (similar to buprenorphine 2 mg tablet prepared by the Faculty of Pharmacy) starts sublingual with one tablet daily and will be increased to 2 tablets per day and then continued for one month. And then it gradually declined and stopped within two weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid hospital and wellfaer esfahan
Full name of responsible person
Dr.Gholamreza kheirabadi
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Sponsors / Funding sources

1

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Grant name
reseach deputy of esfahan university of medical sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
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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
Confidentiality

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