Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The assessment of amantadine add-on therapy effects on craving and relapse reduction among patients with methamphetamine dependence.

Protocol summary

Study aim

Determining the average frequency of relapse using urine amphetamine test in the intervention group and in the control group and comparing it in the two groups by correcting the variables of age, sex, and duration of use. Determining the mean score of craving using CCQ questionnaire in the intervention group and in the control group and comparing it in the two groups by correcting the variables of age, sex, and duration of use.

Design

A triple-blinded randomized clinical trial.

Settings and conduct

The patients who will refer to Isfahan Amin Hospital to quit addiction will be divided into two groups, including matrix program plus amantadine versus matrix program plus placebo. The patients, Psychiatry resident, statistician, and the person who supervises the project are blinded to the interventions in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18-60 years old Methamphetamine use disorder only according to DSM-V Willingness for participation in the study Unmet criteria: Use of psychiatric drugs Presence of major psychiatric disorders Major and chronic physical disorders Pregnancy

Intervention groups

The patients will be treated with amantadine in the intervention group or placebo in the control group for two months during the matrix program. The methamphetamine use will be evaluated by urine test weekly during the interventions and then, monthly for four months. The anxiety and depression status of the patients will be evaluated at baseline and within two months after the interventions using the Hospital Anxiety and Depression Scale (HADS).

Main outcome variables

Determining the effect of adding amantadine to Matrix treatment program on reducing craving and relapse in methamphetamine-dependent patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N16**
Registration date: **2022-02-09, 1400/11/20**
Registration timing: **prospective**

Last update: **2022-02-09, 1400/11/20**
Update count: **0**

Registration date

2022-02-09, 1400/11/20

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2135

Email address

kheirabadi@bsrc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of amantadine add-on therapy effects on craving and relapse reduction among patients with methamphetamine dependence.

Public title
Amantadine in methamphetamine-dependent patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18-60 years old patients The participants who meet the criteria of methamphetamine use disorder based on DSM-V Only depend on methamphetamine Patients' satisfaction for participation in the study
Exclusion criteria:
Psychiatric drugs administration The concurrent major psychiatric disorders such as mood and thinking disorders Major and chronic physical disorders Pregnancy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
After selection, eligible participants are randomly divided (by Block Design Randomization method) into two groups of amantadine and placebo, for both groups a 2-month matrix treatment plan is considered and then will be followed for 4 months.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patients, the Psychiatry resident who is responsible for the project, the statistician, and the person who supervises the project process are blinded to the categorization of the patients into drug versus placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2021-04-30, 1400/02/10
Ethics committee reference number
IR.MUI.MED.REC.1400.078

Health conditions studied

1

Description of health condition studied
Craving and relapse reduction in methamphetamine-dependent patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amantadine add-on therapy effects on craving and relapse reduction among patients with methamphetamine dependence.
Timepoint
Methamphetamine urine test will be done weekly during the intervention and monthly in follow-up period.
Method of measurement
CCQ-Brief Questionnaire

Secondary outcomes

1

Description
Anxiety
Timepoint
Before and 2 months after the Intervention.
Method of measurement
Hospital Anxiety - Depressive Scale.

2

Description
Depression
Timepoint
Before and 2 months after the Intervention.
Method of measurement
Hospital Anxiety - Depressive Scale.

Intervention groups

1

Description
Intervention group: The intervention group will be treated with a daily dose of 100 mg amantadine capsules (Hakim, Iran) that will be increased by 100 mg every week to achieve the maximum daily dose of 300 mg (100 mg every 8 hours); if tolerated by the patients. The matrix program will be performed for two months with the latest dose and by the end of the program, the medication will be ceased. In case who cannot tolerate the maximum dose, the medication will be performed by the highest tolerable dose. The patients will be assessed using urine methamphetamine and other drugs tests weekly during the program and then, monthly in the follow-up period.

Category
Treatment - Drugs

2

Description
Control group: The control group will be intervened with a capsule made by the Pharmacy faculty similar to the amantadine. They will administer the medication for two months. The assessments are similar to the intervention group that will be weekly during the matrix program period and then, monthly in the follow-up period using urine methamphetamine and other drugs urine test.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Addiction Treatment Center of Amin Hospital, Isfahan.

Full name of responsible person
Gholamreza Kheirabadi

Street address
Amin Hospital, Sanbolistan Alley, Ibn Sina St, Isfahan

City
isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
kheirabadi@bsrc.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Gholamreza Kheirabadi

Street address
Vice chancellor for research, Isfahan University of Medical Sciences; Faculty of Medicine; Isfahan University of Medical Sciences; Hezar-Jarib Street; Isfahan; Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
kheirabadi@bsrc.mui.ac.ir

Grant name

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
Gholam Reza Kheirabadi

Position
Professor of Psychiatry

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Behavioral Sciences Research Center, Khorshid Hospital, Isfahan University of Medical Sciences, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 1222 2135

Fax
+98 31 1222 2135
Email
kheirabadi@bsrc.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Position
Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Behavioral Sciences Research Center, Isfahan University of Medical Sciences, Isfahan, Iran
City
isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 1222 2135
Fax
+98 31 1222 2135
Email
kheirabadi@bsrc.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Kheirabadi
Position
Professor of Psychiatry
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Behavioral Sciences Research Center, Khorshid Hospital, Isfahan University of Medical Sciences, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 1222 2135
Fax
+98 31 1222 2135
Email
kheirabadi@bsrc.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The data relating to the major outcomes are partly available.
When the data will become available and for how long
Access initiation from 1401
To whom data/document is available
All academic researchers
Under which criteria data/document could be used
Analysis other than those listed in the methodsection is not allowed.
From where data/document is obtainable
Correspondence by e-mail
What processes are involved for a request to access data/document
Requests should be proposed by e-mail with signature and statement of the subject
Comments