

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

Isfahan

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

Isfahan

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

Isfahan

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

Isfahan

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
Isfahan
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
Isfahan
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