

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Placebo-controlled randomized clinical trial testing the efficacy of desipramine in reducing craving in patients with methamphetamine use disorder

Protocol summary

Study aim

We will test the hypothesis that desipramine is effective in reducing methamphetamine craving in patients with the diagnosis of methamphetamine use disorder.

Design

A single-site double-blinded randomized placebo-controlled phase 2 trial on 40 patients

Settings and conduct

40 patients referring to the outpatient addiction clinic of Iran psychiatric hospital willing to receive matrix model therapy for methamphetamine addiction and willing to participate in the study who are eligible will be divided into two groups receiving desipramine or placebo for 12 weeks. An independent researcher will prepare the sequentially numbered envelopes with a code and the corresponding pills for the duration of the study. The corresponding researcher will allocate a participant to an unknown group based on the code and the containing of the opaque sealed envelop. The treatment team, the corresponding researcher and patients will all be blind to the allocated groups.

Participants/Inclusion and exclusion criteria

Male patients with the current diagnosis of methamphetamine use disorder aged 18 to 55 will be included. Patients will be excluded if: they have condition known to be deteriorated with desipramine use, have other psychiatric disorders requiring in patient care, have other medical conditions, have medication intolerance or they are not willing to continue participating.

Intervention groups

In the intervention group as the matrix model treatment begins, desipramine will be started at the dose of 50 mg per day and gradually increased to 100 mg per day and will be continued for 12 weeks. In the control group as the matrix model treatment starts, placebo will be administered in the same manner and continued for 12 weeks.

Main outcome variables

positive urine test for methamphetamine; visual analog scale score for craving; methamphetamine craving questionnaire-Brief score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029315N2**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **retrospective**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

Mohammad Reza Najarzadegan

Name of organization / entity

Iran University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Behavioral Sciences Research Center of Iran University of Medical Sciences, Medical University of Iran University of Medical Science

Expected recruitment start date

2016-06-03, 1395/03/14
Expected recruitment end date
 2017-03-03, 1395/12/13
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Placebo-controlled randomized clinical trial testing the efficacy of desipramine in reducing craving in patients with methamphetamine use disorder

Public title
 The efficacy of desipramine in reducing methamphetamine craving

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 18 to 50 Current diagnosis of methamphetamine use disorder based on DSM IV-TR criteria Positive urine test for methamphetamine prior to study entry Male gender
Exclusion criteria:
 Having conditions known to be deteriorated following desipramine use such as obesity, liver diseases, and cardiovascular diseases Taking antidepressants of any class in during the two weeks prior to entering the study Taking medications with potential effect on methamphetamine craving (i.e. modafinil, bupropion, naltrexone, N-acetylcysteine) Taking medications known to adversely interact with desipramine Serious mood disorders, suicidal ideation, and psychotic disorders requiring hospitalization Comorbid medical conditions, as revealed by history review, physical exam, or laboratory results of blood chemistry test and liver profile Incidence of a life-threatening side effect following medication use (i.e. liver failure, pancreatitis, hepatic encephalopathy, thrombocytopenia, leucopenia) Medication intolerance Use of other substances (except methadone maintenance therapy, nicotine, cannabis, and morphine) confirmed by a toxicology screen Currently (during a month prior to study) in treatment for methamphetamine use Having DSM IV-TR diagnosis of other substance use disorders in the past year No longer willing to participate in the study

Age
 From **18 years** old to **50 years** old

Gender
 Male

Phase
 2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**
Randomization (investigator's opinion)
 Randomized
Randomization description
 An independent researcher will randomly allocate eligible participants to treatment vs. placebo group by block randomization method with random block size using Random Allocation Software version 1.0.0. Generated codes with the associated pills (desipramine or placebo) will be inserted into opaque sealed envelopes.
Blinding (investigator's opinion)
 Double blinded
Blinding description
 All patients, the corresponding researcher, physicians, nurses, people responsible to gather data, and individuals who evaluate outcomes will be blinded to the allocations.
Placebo
 Used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

5th floor, central head quarter, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2015-06-25, 1394/04/04

Ethics committee reference number

IR.IUMS.REC 1394.92-11-28-6006

Health conditions studied

1

Description of health condition studied

Metamphetamine use disorder

ICD-10 code

F15.20

ICD-10 code description

Other stimulant dependence, uncomplicated

Primary outcomes

1

Description

Metamphetamine craving

Timepoint

before intervention, at the end of each month after intervention until 4 months (0-1-2-3-4)

Method of measurement

Cocaine Craving Questionnaire-Brief

2

Description

Positive urine toxicology test for methamphetamine

Timepoint

Before intervention, at the end of each month after intervention until 4 months (0-1-2-3-4)

Method of measurement

Urine toxicology test

Secondary outcomes

1

Description

Drug Side Effects

Timepoint

Before intervention and at the end of each month after intervention until 4 months (0-1-2-3-4)

Method of measurement

Side effects questionnaire

Intervention groups

1

Description

Intervention group: Half of participants will be treated by desipramine (Exir pharmaceutical company) at the dose of 50 mg once per day orally and gradually increasing to 100 mg once per day and continued for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Half of participants will receive placebo. Placebo will be started identically as the shape of desipramine with the dose of 50 mg once per day orally and gradually increased to 100 mg once per day and continued for 12 weeks. Placebo and desipramine will be of the same shape, appearance, size, texture, color, and odor.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient clinic of Iran psychiatry hospital

Full name of responsible person

Dr. Hamidreza Ahmadkhaniha

Street address

7th km Karaj road, Iran psychiatric hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mental Health Research Center

Full name of responsible person

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Street address

1st floor, Tehran Psychiatric Institute, Mansouri street, Niyayesh street, Sattarkhan

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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

Mental Health Research Center

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

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Ahmadkhaniha

Position

Associate Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Ila Daryoushfar

Position

Resident of Psychiatry

Latest degree

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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 SPSS file containing data of participants is sharable.

When the data will become available and for how long

Data will be shared 6 months after publishing the results.

To whom data/document is available

Researchers could request to receive the data.

Under which criteria data/document could be used

Various analysis based of sample size is performable.

From where data/document is obtainable

To receive data one should email the corresponding researcher.

What processes are involved for a request to access

data/document

Two weeks after an inquiry email one would receive the

data.

Comments