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

Iran (Islamic Republic of)

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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
Metamphemine 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
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7th km Karaj road, Iran psychiatric hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Academic

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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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