

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of two therapies methylphenidate and matrix-methylphenidate on the severity of addiction, craving and treatment abstinence in methamphetamine abusers

Protocol summary

Study aim

The aim of this study is comparison of the effect of two therapies methylphenidate and matrix-methylphenidate on the severity of addiction, craving, relapse and mental health in methamphetamine abusers.

Design

In this research, 100 eligible patients with methamphetamine dependency diagnosis according to DSM-IV criteria are enrolled and a code was allocated to each one of them. Then, random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

100 eligible patients methamphetamine abuse referred to Farabi Hospital affiliated to Kermanshah University of Medical Sciences, Kermanshah, Iran will be selected in the study. No blind design and factorial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: methamphetamine dependence diagnoses accordingly Diagnostic and Statistical Manual of Mental Disorders. Exclusion criteria: Unwillingness to cooperate

Intervention groups

Patients will be divided into four treatment groups: matrix, methylphenidate, matrix-methylphenidate and control group. The first group (25 people) will be treated individuals, for 22 sessions of 45 minutes, twice a week for three months for matrix treatment. The second group (25 people) will receive methylphenidate 10 mg/day in the first month, 7.5 mg/day in the second month and 5 mg/day in the third month. The third group (25 people) matrix combination with methylphenidate and in the group control (25 people) there is no intervention.

Main outcome variables

Addiction severity and craving (primary outcomes)
Mental health and relapse (secondary outcome)

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20171105037245N1**

Registration date: **2017-12-09, 1396/09/18**

Registration timing: **retrospective**

Last update: **2020-07-11, 1399/04/21**

Update count: **1**

Registration date

2017-12-09, 1396/09/18

Registrant information

Name

Nazanin Arian

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 3826 4513

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-10-14, 1396/07/22

Expected recruitment end date

2017-11-13, 1396/08/22

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of two therapies methylphenidate and matrix-methylphenidate on the severity of addiction, craving and treatment abstinence in methamphetamine abusers

Public title
Comparison of the effect of two therapies methylphenidate and matrix-methylphenidate in methamphetamine abusers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
being at the age of 20 to 48 years Methamphetamine dependence diagnoses accordingly Diagnostic and Statistical Manual of Mental Disorders fifth edition The dominant use of methamphetamine Seeking treatment for methamphetamine abuse
Exclusion criteria:
Unwillingness to participate in the study Having severe psychotic disorders Suicide attempts within the past 12 months Major cardiovascular disorder Epilepsy Current alcohol or sedative physical dependence or cocaine dependence

Age
From **20 years** old to **48 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.Kaums.REC.1396.59

Health conditions studied

1

Description of health condition studied

Methamphetamine Dependency

ICD-10 code

F15.15

ICD-10 code description

Other stimulant abuse with stimulant-induced psychotic disorder

Primary outcomes

1

Description

Addiction Severity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Addiction Severity Index

2

Description

Craving

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Desire for Drug Questionnaire (DDQ craving)

Secondary outcomes

1

Description

Mental health

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

General Health Questionnaire (GHQ)

2

Description

Negative urine test for methamphetamine

Timepoint

Before intervention and 3, 6, 9 and 12 weeks after intervention

Method of measurement

Methamphetamine urine test

Intervention groups

1

Description

The Matrix program, which consists of 22 sessions of cognitive and behavioral psychotherapy, will be performed weekly in two sessions of forty five minutes for 12 weeks.

Category

Behavior

2

Description

Methylphenidate (Ritalin) will be given 10 mg per day in first month, 7.5 mg per day for second month and 5 mg per day for third month

Category

Treatment - Drugs

3

Description

Combining matrix and methylphenidate treatment (The Matrix program, which consists of 22 sessions of cognitive and behavioral psychotherapy, will be performed weekly in two sessions of forty five minutes for 12 weeks and methylphenidate (Ritalin) will be given 10 mg per day in first month, 7.5 mg per day for second month and 5 mg per day for third month)

Category

Treatment - Other

4

Description

Control group (not receiving any psychological educational services and drugs)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faraby Hospital Substance Dependency Clinic

Full name of responsible person

Nazanine Arian

Street address

First floor, No. 7, Farabi Hospital, Isar Blvd., Kermanshah

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arian-n@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Abdollah Omid
Position
PhD of Clinical Psychology
Latest degree
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Other areas of specialty/work
Psychology
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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

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

Undecided - It is not yet known if there will be 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