Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effectiveness of mirtazapine in reducing dependence and the temptation to consume amphetamine and methamphetamine patients referred to addiction treatment clinics

Protocol summary

Study aim

Investigating the effectiveness of mirtazapine in reducing dependence and the temptation to consume amphetamine and methamphetamine patients referred to addiction treatment clinics

Design

A double-blind, placebo-controlled trial to evaluate the effect of mirtazapine compared to placebo. Two groups of 42 people are divided into control and intervention groups. The intervention group is treated with mirtazapine tablets with a dose of 15 mg, and the control group is treated with a placebo with the same shape, smell, taste and usage as mirtazapine. After one week, the drug consumption is doubled in both groups. The drug is taken at night and will last for 12 weeks.

Settings and conduct

84 patients referred to Ahvaz city are diagnosed by a psychiatric specialist based on DSM V diagnostic criteria. The control group will be treated with a placebo with the same shape, smell, taste and usage as Mirtazapine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least one positive urine test for methamphetamine during the hospitalization period Absence of current acute illness that requires long-term medical care Exclusion criteria: Diagnosis of psychotic disorder by SCID-5 Diagnosis of Major Depressive Disorder by SCID-5 Known hypersensitivity or previous adverse reaction to mirtazapine

Intervention groups

The intervention group will be treated with mirtazapine tablets at a dose of 15 mg per day. The control group will be treated with a placebo with the same shape, smell, taste and usage as mirtazapine.

Main outcome variables

Dependence and temptation to consume patients

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20230606058397N1**
Registration date: **2023-09-18, 1402/06/27**
Registration timing: **prospective**

Last update: **2023-09-18, 1402/06/27**
Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Mohammad Hossein Salehi Kasaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3343 3213

Email address

ehsanmoradijoo@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-01-22, 1402/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effectiveness of mirtazapine in reducing dependence and the temptation to consume amphetamine and methamphetamine patients referred to addiction treatment clinics

Public title
The effectiveness of mirtazapine in reducing dependence and the temptation to consume amphetamine and methamphetamine in patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
At least one positive urine test for methamphetamine during the hospitalization period Absence of current acute illness Absence of serious chronic diseases Able and willing to provide informed consent and adhere to the visit schedule
Exclusion criteria:

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
First, by using the Random number generation plugin in Excel software, a table of random numbers from 1 to 84 is prepared in a non-sequential and scattered manner, and intervention and control is done by assigning numbers to two groups of 42 people. The randomization process is done by the study methodology consultant, and the clinical researchers do not know about the randomization process, and only randomized codes from 1 to 84 will be provided to them.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind, placebo-controlled trial to evaluate the effect of mirtazapine compared to placebo in reducing the use of amphetamine and methamphetamine. The intervention group will be treated with mirtazapine tablets at a dose of 15 mg per day. The control group will be treated with a placebo with the same shape, smell, taste and usage as mirtazapine. After one week, the drug consumption in both groups was doubled, so that patients in the mirtazapine group took two 15 mg tablets (30 mg in total) and patients in the placebo group took two placebo tablets. The medicine is taken at night and will last for twelve weeks. In this study, both the participants and the evaluator are unaware of the nature of both groups, on this basis, this study will be conducted in a double-blind manner.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences
Street address
Ahvaz University of Medical Sciences, Golestan Boulevard, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135733118

Approval date
2022-11-15, 1401/08/24

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.141

Health conditions studied

1

Description of health condition studied
Methamphetamine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Decreasing addiction in patients using amphetamine and methamphetamine.

Timepoint
Before starting the treatment, at the beginning of the treatment and once every two weeks (the length of the treatment is 12 weeks), the results will be measured.

Method of measurement
With physical examinations and measurement of vital signs, evaluation with the dependency index questionnaire.

Secondary outcomes

1

Description
Reducing depression in patients using amphetamine and methamphetamine.
Timepoint
Before starting the treatment, at the beginning of the treatment and once every two weeks (the length of the treatment is 12 weeks), the results will be measured.
Method of measurement
with Beck depression questionnaire, physical examinations and measuring vital signs

Intervention groups

1

Description
Intervention group: 84 patients referred to Golestan hospital clinic, who were diagnosed by a psychiatric specialist based on DSM V diagnosis criteria, entered the study and were randomly assigned to one of two intervention or placebo groups. After explaining the plan to the patients, if they give their consent and complete the informed consent form, taking into account the entry and exit criteria, based on the random list prepared by the statistical consultant, they will be divided into two groups of 42 people, control and intervention. The intervention group will be treated with mirtazapine tablets at a dose of 15 mg per day. The control group will be treated with a placebo with the same shape, smell, taste and usage as mirtazapine. After one week, the drug consumption in both groups was doubled, so that patients in the mirtazapine group took two 15 mg tablets (30 mg in total) and patients in the placebo group took two placebo tablets. The medicine is taken at night and will last for twelve weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital Clinic
Full name of responsible person
Mohammad Hossein Saleh Kasai
Street address
Golestan Hospital, Balwaz Golestan, Ahvaz
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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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itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Hossein Salehi Kasai
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
There is no problem with publishing
When the data will become available and for how long
1403
To whom data/document is available
Group of psychiatrists
Under which criteria data/document could be used
The documents and data of this study can be analyzed if it is limited to the population inside Khuzestan province and this research cannot be generalized for other regions. It can be used if you only have documents and references.
From where data/document is obtainable
Research Vice-Chancellor of Jundishapur University of Medical Sciences, Ahvaz medical School Psychiatry department located in Golestan Blvd, Golestan Hospital, Ahvaz. Postal code 61357-15794 Internet address journal_ajums@yahoo.com 06133113828
What processes are involved for a request to access data/document
He should write a letter to the university security through the vice president of research and finally receive the documents through the vice president himself. This process takes about a week.
Comments
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