

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

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##### 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

Khuzestan

##### 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

ehsanmoradijoo@yahoo.com

### 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

##### City

Ahvaz

##### Province

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##### Postal code

6135733118

##### Phone

+98 930 202 6539

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mehrnoosh Zakirkish

##### Street address

Ahvaz University of Medical Sciences, Golestan Boulevard, Ahvaz

##### City

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##### Phone

+98 61 3336 1544

##### Email

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

Psychiatrics

##### Street address

Golestan Hospital, Golestan Boulevard, Ahvaz

##### City

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##### Province

Khouzestan

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Ahmed Fakhri  
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Associate professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
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**Province**  
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**Email**  
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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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