

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparing the Atomoxetine effectiveness in retention of patients in the stimulant (Meth-Amphetamine) dependence treatment with placebo in a three month period

#### Protocol summary

##### Summary

The main objective of this study is to compare effectiveness of atomoxetine with placebo in treatment of amphetamine-type stimulants (methamphetamine). The study is a triple-blind multi-center, phase 2, randomized controlled trial in which 90 clients with amphetamine-type stimulants use disorder will randomly assign to one of three groups including atomoxetine 120mg/d, atomoxetine 60 mg/day or placebo for three months. Inclusion criteria are having stimulant (methamphetamine) use disorder according to DSM-5, using 2 times or more methamphetamine in a week during last month and age 18 to 60 years old. The exclusion criteria are sensitivity to atomoxetine, rising of liver enzymes more than 3 times: hepatic failure, acute hepatitis, having other substance use disorders (except nicotine) and using MAOI medications during last 2 weeks. All participants will receive basic psychological interventions. Primary outcome of the study is retention in treatment and secondary outcomes of the study are methamphetamine abstinence measured by urine tests and self-report and addiction severity measured by Addiction Severity Index (ASI).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070234844N1**  
Registration date: **2017-07-19, 1396/04/28**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-07-19, 1396/04/28

#### Registrant information

##### Name

Alireza Noroozi

##### Name of organization / entity

Iranian National Center for Addiction Studies (INCAS)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5542 1144

##### Email address

noroozi\_a@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences (TUMS), Vice-chancellor for Research

#### Expected recruitment start date

2017-08-23, 1396/06/01

#### Expected recruitment end date

2018-11-22, 1397/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the Atomoxetine effectiveness in retention of patients in the stimulant (Meth-Amphetamine) dependence treatment with placebo in a three month period

#### Public title

Effectiveness of Atomoxetine treatment for methamphetamine use disorder

#### Purpose

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1- Diagnosis of methamphetamine use disorder based on DSM-5; 2- Using methamphetamine 2 times or more in week during last month; 3- Age: 18 to 60 years old; 4. Referring to Psychiatric Clinic of Roozbeh Hospital or Iranian National Center for Addiction Studies (INCAS) Clinic Exclusion criteria: 1. Sensitivity to Atomoxetine; 2. Rising liver enzymes more than three times; Hepatic failure, acute hepatitis; 3. Other substance use disorders including alcohol, opioids and sedative and hypnotic medications (except nicotine); 4. More than 2 times illicit opioid use during last month; 5. Use of mono-amine oxidase inhibitor (MAOI) medications during last 2 weeks; 6. Severe cardiac disorder, history of MI during last month, uncontrolled hypertension (HTN); 7. Pregnancy or breastfeeding; 8. Risk of suicide, homicide or violence; 9. Psychosis; 10. Unable to comprehend study protocol and answer questionnaires; 11. Receiving opioid agonist medications such as MMT.

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic Committee of Tehran University of Medical Sciences (TUMS), Vice-chancellor for Research

**Street address**

6th Floor, Central Building of Tehran University of Medical Sciences (TUMS), Ghods St., Keshavarz Blv.

**City**

Tehran

**Postal code****Approval date**

2016-06-21, 1395/04/01

**Ethics committee reference number****Health conditions studied****1****Description of health condition studied**

Other stimulants dependence syndrome

**ICD-10 code**

F15.24

**ICD-10 code description**

Dependence syndrome: A cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite

**Primary outcomes****1****Description**

Retention

**Timepoint**

Weekly

**Method of measurement**

Participation in physician visit/s, psychological treatment sessions and completion of assessments

**Secondary outcomes****1****Description**

Methamphetamine abstinence- Urine tests

**Timepoint**

Weekly

**Method of measurement**

Urine immunoassay test for methamphetamine

**2****Description**

Methamphetamine abstinence- Self-report

**Timepoint**

Weekly

**Method of measurement**

Self-report measured by timeline follow-back (TLFB)

**3****Description**

Addiction severity

**Timepoint**

Monthly

**Method of measurement**

Self-report measured by Addiction Severity Index (ASI)

**Intervention groups**

## 1

### Description

Atomoxetine 120 mg group: Treatment will start with 40 mg/day atomoxetine capsule manufactured by Tadbir Kalay-e Jam Pharmaceutical Company for first week (days 1-7) and will continue with 80 mg/day atomoxetine in second week (days 8-14). The dose will be increased to final dose of 120 mg/day from week 3 (day 15) of treatment. In case of adverse events or intolerance of medication, the rate of dose increase will be decreased. The capsules of this group will be exactly similar to the capsules of other groups. Medication will be prescribed orally, once a day at morning. All patients will receive twice weekly individual basic cognitive, behavioral counselling during the study and after it.

### Category

Treatment - Drugs

## 2

### Description

Atomoxetine 60 mg group: Treatment will start with 20 mg/day atomoxetine capsule manufactured by Tadbir Kalay-e Jam Pharmaceutical Company for first week (days 1-7) and will continue with 40 mg/day atomoxetine in second week (days 8-14). The dose will be increased to final dose of 60 mg/day from week 3 (day 15) of treatment. The capsules of this group will be exactly similar to the capsules of other groups. Medication will be prescribed orally, once a day at morning. All patients will receive twice weekly individual basic cognitive, behavioral counselling during the study and after it.

### Category

Treatment - Drugs

## 3

### Description

Placebo group: Patients will receive placebo capsules which are exactly similar to capsules of other study arms and will be manufactured by Tadbir Kalay-e Jam Pharmaceutical Company. Placebo capsules will include starch. All patients will receive one capsule in first week, 2 capsules in second week and 3 capsules for the rest of study once a day at morning. The patients will receive medication for 12 weeks. After that if they want they could receive medication on open-label basis. All patients will receive twice weekly individual basic cognitive, behavioral treatment during the study and after it.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Iranian National Center for Addiction Studies

##### Full name of responsible person

Alireza Noroozi

##### Street address

No 486, South Kargar St., Qazvin Sq., Next to Farabi Hospital

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Psychiatric Clinic of Roozbeh Hospital

##### Full name of responsible person

##### Street address

South Kargar St, South of Lashgar Crossroad, Roozbeh Hospital

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences (TUMS), Vice-chancellor for Research

##### Full name of responsible person

Ms. Karimi

##### Street address

6th Floor, Central Building of Tehran University of Medical Sciences (TUMS), Ghods St., Keshavarz Blv.

##### City

Tehran

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tehran University of Medical Sciences (TUMS), Vice-chancellor for Research

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iranian National Center for Addiction Studies (INCAS)

##### Full name of responsible person

Dr. Alireza Noroozi

##### Position

Psychiatrist

##### Other areas of specialty/work

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*