

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Randomized clinical trial of the comparison of the effectiveness of topiramate in reducing craving in patients with methamphetamine use disorder

#### Protocol summary

##### Study aim

The purpose of this study is to test the hypothesis that topiramate 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 2-3 trial on 56 patients

##### Settings and conduct

56 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 topiramate or placebo for 24 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, patients, and data analyzer will all be blind to the allocated groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65, diagnosis of methamphetamine use disorder, Positive urine test/self report, BMI $\geq$ 18; exclusion criteria: Comorbid medical/psychiatric conditions, Use of medications affecting craving, pregnancy/lactation, seizure, glaucoma

##### Intervention groups

In the intervention group as the matrix model treatment begins, topiramate (Arya Pharmaceutical Company) will be started at the dose of 25 mg/day and gradually increased over 45 days to 300 mg per day (or the maximum tolerated dose less than 300) and will be continued for 24 weeks. In the control group as the matrix model treatment starts, placebo (Arya Pharmaceutical Company) will be administered the same

way and is continued for 24 weeks.

##### Main outcome variables

Positive urine test for methamphetamine; stimulant craving questionnaire score; addiction severity index compisite score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180929041167N1**  
Registration date: **2022-09-19, 1401/06/28**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-19, 1401/06/28**

Update count: **0**

##### Registration date

2022-09-19, 1401/06/28

##### Registrant information

##### Name

Hamidreza Ahmadkhaniha

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4450 3395

##### Email address

dr\_ahmadkhaniha@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-22, 1398/04/31

##### Expected recruitment end date

2023-06-21, 1402/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Randomized clinical trial of the comparison of the effectiveness of topiramate in reducing craving in patients with methamphetamine use disorder

**Public title**

The effectiveness of topiramate in reducing methamphetamine craving

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 18 to 65 years Current diagnosis of methamphetamine use disorder based on DSM-V criteria Positive urine test for methamphetamine prior to study entry or self report of methamphetamine use for at least 5 days during the previous month Body mass index equal or greater than 18

**Exclusion criteria:**

Comorbid medical conditions based on medical history, physical examination, and laboratory test results Use of other substances (except for methadone as a maintenance therapy, nicotine, and cannabis) confirmed by toxicology screening Use of medications known to interact with topiramate such as acetazolamide, ergotamines, simvastatin, lovastatin, and antiepileptics History of hypersensitivity to topiramate Impaired renal function History of kidney stone Serious mood disorders (i.e. major depressive disorder, bipolar disorder), suicidal ideation, schizophrenia, psychosis (except for transient psychosis due to substance use), dementia, psychiatric disorders requiring psychotropic medications (except for medication for insomnia) Use of medications with potential effect on methamphetamine craving (i.e. modafinil, bupropion, naltrexone, N-acetylcysteine) Pregnancy and or lactation Currently (during a month prior to the study) in treatment for methamphetamine use Having DSM-V diagnosis of any other substance use disorders in the previous year Coronary vascular disease confirmed by physical examination and electrocardiography History of seizure History of glaucoma Having DSM-V axis I psychiatric disorders that will probably need treatment during the study duration or that are unstable Patients referred by court seeking treatment for penalty rebate

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

- Outcome assessor

- Data analyser

**Sample size**

Target sample size: **56**

**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 (2, 4,8) using Random Allocation Software version 1.0.0. Generated codes with the associated pills (topiramate or placebo) will be inserted into opaque sealed envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study placebo would be used. All patients, the corresponding researcher, physicians, nurses, people responsible to gather data, individuals who perform the statistical analysis, and individuals who evaluate outcomes will be blinded to the allocations. All patients will be identified by the code that has been assigned to them in the beginning of the study. The group that individuals are allocated to will be hidden from everyone except for the independent researcher (person responsible for randomization) until the study ends. At the end of the study the independent researcher who has the codes and the treatment teams assigned to them would reveal the groups to which the patients were assigned. Placebo produced by Arya pharmaceutical company is in an identical shape as of Topiramate. Placebo and topiramate will be of the same shape, appearance, size, texture, color, and odor.

**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**

2020-01-13, 1398/10/23

## Ethics committee reference number

IR.IUMS.REC.1398.1031

## 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

Metamphetamine craving

#### Timepoint

Before intervention, at the end of each month after intervention until 6 months (0-1-2-3-4-5-6)

#### Method of measurement

Stimulant craving questionnaire

### 2

#### Description

Positive urine toxicology test for methamphetamine

#### Timepoint

Before intervention, at the end of each month after intervention until 6 months (0-1-2-3-4-5-6)

#### Method of measurement

Urine toxicology test

### 3

#### Description

Addiction severity index composite score

#### Timepoint

Before intervention, at the end of each 3 months after intervention until 6 months (0-3-6)

#### Method of measurement

Addiction severity index-composite

## Secondary outcomes

### 1

#### Description

Drug Side Effects

#### Timepoint

Before intervention and at the end of each month after intervention until 6 months (0-1-2-3-4-5-6)

#### Method of measurement

Drug side effects questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Half of the participants will be treated by topiramate (Aryia pharmaceutical company). The medication will start at the dose of 25 mg once per day orally and gradually increasing to 300 mg once per day over 45 days and will be continued for 24 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Half of participants will receive placebo. Placebo produced by Arya pharmaceutical company in an identical shape as of Topiramate will be started at the dose of 25 mg once per day orally and gradually increased to 300 mg once per day over 45 days and continued for 24 weeks. Placebo and topiramate will be of the same shape, appearance, size, texture, color, and odor.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Outpatient clinic of Iran psychiatry hospital

##### Full name of responsible person

Dr. Hamidreza Ahmadkhaniha

##### Street address

Iran psychiatric hospital, 7th km Karaj road

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Hossein Keyvani

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Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway, Tehran

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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**  
Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Dr. Hamidreza Ahmadkhaniha  
**Position**  
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Specialist  
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## Person responsible for scientific inquiries

**Contact**  
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Research center for addiction and risky behaviors  
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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**  
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****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**

Several methods of analysis can be done on the data based on the final number of sample size.

**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**