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>=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 hypersensetivity to topiramate Impaired renal function History of kidney stone Serious mood disorders (i.e. major depressive disorder, bipolar disorder), suicidal ideation, schizophrenia, psychosis (exept for transient psychosis due to substance use), dementia, psychiatric disorders requiring psychotropic medications (exept for medication for insomnia) Use of medications with potential effect on methamphetamine craving (i.e. modafinil, bupropion, naltrexone, N-acetylcycteine) 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 glucoma Having DSM-V axis I psychiatric disorders that will probabely need treatment during the study duration or that are unstable Patients referred by court seeking treatment for penatly 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
Metamphemine 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 identicall 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
City
Tehran
Province
Tehran
Postal code
۱۳۹۸۹۱۳۱۵۱
Phone
+98 21 4450 3395
Fax
+98 21 4450 3401
Email
iph.iranhospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Hossein Keyvani
Street address
Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway، Tehran
City

Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2503

Email
keyvani.h@iums.ac.ir

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
Associate Professor of Psychiatry

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Iran Psychiatric Hospital, 7th km Karaj Special Road

City
Tehran

Province
Tehran

Postal code
1398913151

Phone
+98 21 4452 5615

Email
dr_ahmadkhaniha@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Research center for addicition and risky behaviors

Full name of responsible person
Hasti Hadizadeh

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
1st floor, Tehran Psychiatric Institute, Mansouri street, Niyayesh street, Sattarkhan

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 6650 6862

Email
hasti.hadizadeh.d@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Research center for addiction and risky behaviors

Full name of responsible person
Hasti Hadizadeh

Position
Researcher

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
1st floor, Tehran Psychiatric Institute, Mansouri street, Niyayesh street, Sattarkhan

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 6650 6862

Email
hasti.hadizadeh.d@gmail.com

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

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