

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effectiveness of topiramate in treating dependence of amphetamine and methamphetamine patients

Protocol summary

Study aim

Evaluation of the effectiveness of topiramate in treating dependence of amphetamine and methamphetamine patients

Design

Phase 2-3 clinical trial study with parallel, double-blind and randomized groups based on randomized block permutation method.

Settings and conduct

Phase 2-3 clinical trial study with parallel, double-blind and randomized groups based on randomized block permutation method. The patient and the evaluator in this study are not aware of the medication received. The study site is located in Ahvaz city, Khuzestan province.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 55 years, with amphetamine and methamphetamine use disorder
Exclusion criteria: History of major psychiatric disorder, existence of harmful thoughts to oneself and others, existence of underlying medical illness, history of receiving psychiatric medication during the last 3 months, BMI less than 18, pregnant woman or breast feeding.

Intervention groups

The intervention group includes patients with amphetamine and methamphetamine use disorders to treat dependence with topiramate tablets with a starting dose of 50 mg per day and the dose of the drug is increased weekly and continues until the target dose of 200 mg. The control group includes patients with amphetamine and methamphetamine disorders receiving placebo intervention. The placebo is similar to topiramate in appearance, color, odor, and dosage.

Main outcome variables

Intensity of dependence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160417027437N2**
Registration date: **2021-07-19, 1400/04/28**
Registration timing: **prospective**

Last update: **2021-07-19, 1400/04/28**

Update count: **0**

Registration date

2021-07-19, 1400/04/28

Registrant information

Name

Amirali Moghaddam Sadegh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

moghaddam.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of topiramate in treating dependence of amphetamine and methamphetamine

patients

Public title

Evaluation of the effectiveness of topiramate in treating dependence of amphetamine and methamphetamine patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients aged 18-55 years With amphetamine and methamphetamine use disorders

Exclusion criteria:

History of major psychiatric disorder existence of harmful thoughts to oneself and others history of receiving psychiatric medication during the last 3 months pregnant woman or breast feeding BMI less than 18

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups.

According to that, there are 2 treatments, for every block a different random order will be prepared. Random table was used as the randomization tool.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher and the patients are unaware of which drug or placebo they receive in either group. Medications and placebos will be similar in shape, color, and taste

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Junishapur University of Medical Sciences

Street address

Golestan Blvd, Ahvaz, Khoozestan

City

Ahvaz

Province

Khoozestan

Postal code

6135715794

Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.015

Health conditions studied

1

Description of health condition studied

drug abuse

ICD-10 code

Other psyc

ICD-10 code description

F19

Primary outcomes

1

Description

Intensity of dependence

Timepoint

Weeks 2, 4, 6, 8, 10 and 12 after the intervention

Method of measurement

McLellan Dependency Index Questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

Weeks 2, 4, 6, 8, 10 and 12 after the intervention

Method of measurement

Beck Depression Inventory

Intervention groups

1

Description

Intervention group: To treat amphetamine and methamphetamine dependence, topiramate tablets are started at a dose of 50 mg per day, the dose is increased weekly until the 12th week to reach a dose of 200. This pill will be provided by Aria Pharmacy.

Category

Treatment - Drugs

2

Description

Control group: For the treatment of amphetamine and methamphetamine dependence, placebo is started at a dose of 50 mg per day, the dose is increased weekly until the 12th week to reach a dose of 200. This pill is supervised and will be provided by the Faculty of Pharmacy, Ahvaz University of Medical Sciences.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Amir Ali Moghadam Sadegh

Street address

Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz

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6135715794

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moghaddam.a@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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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

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

Amir Ali Moghadam Sadegh

Position

استاديار

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Amir Ali Moghadam Sadegh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Province

Khouzestan

Postal code

6135715794

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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