

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Efficacy of Atomoxetine for methamphetamine users who are on methadone maintenance treatment(Randomized, double-blind, placebo-controlled clinical trials)

#### Protocol summary

##### Summary

The aim of study is to evaluate the efficacy of atomoxetine in treating methamphetamine dependency. 82 patients with methamphetamine dependency diagnosis according to DSM IV criteria are enrolled. Patients are divided into two groups by using permuted block randomization. Each group is consisted of 41 people. . The first group will receive atomoxetine 40 mg daily for 8 weeks. The second group will receive placebo for 8 weeks methamphetamine withdrawal symptoms is evaluated with Amphetamine withdrawal questionnaire (AWQ) and Craving is evaluated with VAS and desire of drug questionnaire (DDQ)every ten days. Methamphetamine urine test also is done twice a week. Inclusion Criteria are METH dependence, as assessed by the substance abuse section of the Structured Clinical Interview for DSM-IV65-18 : years old and Exclusion Criteria are documented hypersensitivity to atomoxetine! severe hepatic impairment! hypertension! seizure disorders and Suicide attempts within the past 12 months .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041627413N1**  
Registration date: **2016-05-21, 1395/03/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-21, 1395/03/01

##### Registrant information

Name

Ali Rabiey

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 341 2457

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of Atomoxetine for methamphetamine users who are on methadone maintenance treatment(Randomized, double-blind, placebo-controlled clinical trials)

##### Public title

Efficacy of atomoxetine in methamphetamine dependency

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria:18-65 years old! On Methadone maintenance treatment! Seeking treatment for METH use! METH dependence, as assessed by the substance

abuse section of the Structured Clinical Interview for DSM-IV: At least weekly self-reported METH use during a preceding three month period: Women of childbearing age must have a negative pregnancy test, agree to adequate contraception to prevent pregnancy during the study, agree to monthly pregnancy testing, and not be nursing: Men must agree to use effective means of contraception during the study. Exclusion Criteria: Suicide attempts within the past 12 months or either suicidal ideations or psychotic symptoms in the past 6 months as determined by a study physician: Current opioid, alcohol or sedative physical dependence or cocaine dependence: Major cardiovascular disorder that contraindicates study participation (e.g., history of myocardial infarction, stroke, congestive heart failure, cardiac arrhythmia, hypertension [i.e., > 160 SBP or > 100 DBP] or an unstable medical condition (e.g., untreated bacterial infection) as determined by the study physician: Schizophrenia or bipolar disorder of any type: present or recent use (within 2 weeks) of over-the-counter or prescription drug that would be expected to have major interaction with atomoxetine (e.g., an monoamine oxidase inhibitor (MAOI), paroxetine, fluoxetine, quinidine, dopamine, albuterol, or other  $\beta$ 2-agonists): Medical contraindication to receiving atomoxetine (e.g., severe hepatic impairment, glaucoma, heart disease, hypertension, seizure disorders, documented hypersensitivity to atomoxetine); or other bronchospastic condition, (2nd or 3rd degree AV block, sick sinus rhythm, severe hepatic impairment, documented hypersensitivity to atomoxetine): Liver function tests (i.e., liver enzymes) greater than two times normal levels: Systolic blood pressure of < 90 or > 160 mmHg, diastolic blood pressure of < 60 or > 100 mmHg, or sitting heart rate of < 55 or > 100 beats/min or blood pressure readings > 140 systolic or > 90 diastolic on three separate, consecutive occasions: History of pheochromocytoma: Metabolic diseases such as diabetes and neurological diseases such as epilepsy: Pregnant or nursing female

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **82**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

**1****Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

## Ethics committees

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

Ethics committee of Kashan University of Medical Sciences

**Street address**

Ravandi Boulevard, Kashan University of Medical Sciences, School of Medicine

**City**

Kashan

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

2016-02-25, 1394/12/06

**Ethics committee reference number**

IR.KAUMS.REC.1394.127

## Health conditions studied

**1****Description of health condition studied**

methamphetamine dependence

**ICD-10 code**

F15

**ICD-10 code description**

Mental and behavioural disorders due to use of other stimulants, including caffeine

## Primary outcomes

**1****Description**

Negative urine test for methamphetamine

**Timepoint**

twice a week.

**Method of measurement**

methamphetamine urine test

## Secondary outcomes

**1****Description**

Measure of desire for methamphetamine

**Timepoint**

Once every ten days

**Method of measurement**

by desire for drug questionnaire

**2****Description**

Evaluation of methamphetamine withdrawal symptoms

**Timepoint**

Once every ten days

**Method of measurement**

Methamphetamine Withdrawal Questionnaire

**Intervention groups****1****Description**

The intervention group.: Automoxetine 40 mg daily for 8 weeks.

**Category**

Treatment - Drugs

**2****Description**

the control group:placebo for 8 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Substance abuse treatment centers in Kashan

**Full name of responsible person**

Ali Rabiey

**Street address****City**

Kashan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research,Kashan University of Medical Sciences

**Full name of responsible person**

Dr Gholamali Hamidi

**Street address**

Ravandi boulevard,school of medicine,Kashan University of Medical Sciences

**City**

Kashan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research,Kashan University of Medical Sciences

**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**

kashan university of Medical Sciences

**Full name of responsible person**

Ali Rabiey

**Position**

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## Person responsible for updating data

### Contact

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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*