Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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 automoxetine 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 β2-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
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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
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
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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