

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Survey effect of quetiapine on methamphetamine abuse in patients Methadone Maintenance Treatment

Protocol summary

Study aim

Objective: The aim of study is to evaluate the efficacy of quetiapine in treating methamphetamine dependency.

Design

In this research, 60 eligible patients with methamphetamine dependency diagnosis according to DSM-IV criteria are enrolled and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

60 eligible patients with methamphetamine dependency diagnosis referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18–65 years History of MA and opioid co-abuse in the past year, currently undergoing methadone maintenance treatment, seeking treatment for MA abuse and evaluated by the drug abuse section of the Structured Clinical Interview for DSM-IV and Exclusion Criteria: Suicide attempts within the past 6 months or either suicidal ideations or psychotic symptoms in the past 6 months as determined by a study physician, current alcohol or sedative physical dependence or cocaine dependence, major cardiovascular disturbance and metabolic diseases (e.g., neurological diseases and diabetes).

Intervention groups

The first group will receive quetiapine 100 mg daily for 8 weeks. The second group will receive placebo for 8 weeks.

Main outcome variables

Anxiety, depression, sleep quality, craving, withdrawal and negative urine test for methamphetamine (primary outcomes) and cognitive functions (secondary outcome).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037290N1**

Registration date: **2017-11-25, 1396/09/04**

Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

Registration date

2017-11-25, 1396/09/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 8856

Email address

javdan-na@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-17, 1396/07/25

Expected recruitment end date

2017-11-16, 1396/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Survey effect of quetiapine on methamphetamine

abuse in patients Methadone Maintenance Treatment

Public title
Efficacy of quetiapine in methamphetamine dependency

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18–65 years History of MA and opioid co-abuse in the past year Currently undergoing methadone maintenance treatment Seeking treatment for MA abuse Evaluated by the drug abuse section of the Structured Clinical Interview for DSM-IV
Exclusion criteria:
Suicide attempts within the past 6 months or either suicidal ideations or psychotic symptoms in the past 6 months as determined by a study physician Current alcohol or sedative physical dependence or cocaine dependence Major cardiovascular disturbance Metabolic diseases (e.g., neurological diseases and diabetes).

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfahan

Postal code
8715981151

Approval date
2017-10-12, 1396/07/20

Ethics committee reference number
IR.KAUMS.REC.1396.54

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

Once every fifteen days

Method of measurement

methamphetamine urine test

2

Description

Depression

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Beck Depression Inventory (BDI)

3

Description

Anxiety

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Beck Anxiety Inventory (BAI)

4

Description

Sleep quality

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

5

Description

Craving

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Desire for Drug Questionnaire (DDQ craving)

6

Description

Withdrawal

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Amphetamine Withdrawal Questionnaire (AWQ)

Secondary outcomes

1

Description

Risky Decision Making

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Iowa Gambling Task (IGT)

2

Description

Memory

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Wechsler Logic Memory

3

Description

Verba Fluency

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

FAS task

4

Description

Speed Processing

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Digit Symbol and Trial Making Test (TMT)

Intervention groups

1

Description

Intervention group: Quetiapine 100 mg daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gholabchi Clinic

Full name of responsible person

Najmesadat Javdan

Street address

Shahid Rajaei Avenue, Kashan

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Kashan

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Phone

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javdan-na@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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Grant name

Vice chancellor for research, Kashan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Najmesadat Javdan
Position
PHD Assistant in addiction studies
Latest degree
Master
Other areas of specialty/work
Addiction
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Person responsible for scientific inquiries

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Full name of responsible person
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PhD in Pharmacology-Associate Professor
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
PHD Assistant in addiction studies
Latest degree
Master
Other areas of specialty/work
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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