

# 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 Rajaee Avenue, Kashan

#### City

Kashan

#### Province

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8715981151

#### Phone

+98 31 5554 0021

#### Email

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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Ghotbe Ravandi Boulevard, Kashan

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#### Phone

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hamidi\_gh@kaums.ac.ir

#### 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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Hamid Reza Banafshe  
**Position**  
PhD in Pharmacology-Associate Professor  
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Medical Pharmacy  
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## Person responsible for updating data

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javdan-na@kaums.ac.ir

## 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