

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The efficacy of duloxetine in the treatment of depression, withdrawal symptoms, craving for methamphetamine compared with placebo (clinical trial with a control group)

#### Protocol summary

##### Study aim

Evaluation of the effect of duloxetine in the treatment of depression, withdrawal symptoms, craving for methamphetamine in comparison with placebo (clinical trial study with control group)

##### Design

Clinical trial with control group

##### Settings and conduct

Farabi Hospital in Kermanshah

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Gender Male; Methamphetamine dependence diagnoses accordingly Diagnostic and Statistical Manual of Mental Disorders fifth edition; The dominant use of methamphetamine for at least 6 months, lack of serious psychiatric disorders. Exclusion criteria: Gender female; No use of other drugs and stimulants at the time of entering the study; The absence of comorbid psychiatric disorders symptoms

##### Intervention groups

The experimental group during two months will be treated with duloxetine

##### Main outcome variables

Depression, withdrawal signs, craving

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160717028967N7**

Registration date: **2018-06-29, 1397/04/08**

Registration timing: **prospective**

Last update: **2018-06-29, 1397/04/08**

Update count: **0**

##### Registration date

2018-06-29, 1397/04/08

#### Registrant information

##### Name

Safora Salemi

##### Name of organization / entity

Shahid Chamran University of Ahvaz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3821 1001

##### Email address

e.mahmoudi@cobeldarou.com

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2018-07-21, 1397/04/30

##### Expected recruitment end date

2018-10-22, 1397/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The efficacy of duloxetine in the treatment of depression, withdrawal symptoms, craving for methamphetamine compared with placebo (clinical trial with a control group)

#### Public title

Comparing effects of duloxetine and Placebo on depression, withdrawal symptoms, craving

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

**Inclusion criteria:**

Gender Male Methamphetamine dependence diagnoses accordingly Diagnostic and Statistical Manual of Mental Disorders fifth edition The dominant use of methamphetamine for at least 6 months lack of serious psychiatric disorders

**Exclusion criteria:**

subjects who met opiates dependence non compliance or not willing for continuing the study sever and unbearable drug side effect even after reducing the dose.

**Age**

No age limit

**Gender**

Male

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are divided into two equal groups (A and B) based on a randomized six-block table that is designed by Random allocation software. To conceal the allocation and preservation of blindness, duloxetine and placebo will be placed in similar envelopes in the packed opaque package.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The medication and placebo are delivered to the patient without sticking the label. The doctor is also unaware of the type of drug used in each group. The color and smell of main drug and placebo are the same.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti Blvd, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6719851115

**Approval date**

2018-02-28, 1396/12/09

**Ethics committee reference number**

kums.rec.1396.650

**Health conditions studied**

**1**

**Description of health condition studied**

Methamphetamine dependency

**ICD-10 code**

F16.1

**ICD-10 code description**

Hallucinogen abuse

**Primary outcomes**

**1**

**Description**

Depression

**Timepoint**

before intervention- 4 weeks later- 8 weeks later

**Method of measurement**

Depression Inventory

**2**

**Description**

Withdrawal symptoms

**Timepoint**

before intervention- 4 weeks later- 8 weeks later

**Method of measurement**

Inventory withdrawal symptoms

**3**

**Description**

Craving

**Timepoint**

before intervention- 4 weeks later- 8 weeks later

**Method of measurement**

Craving Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Intervention group: The group will receive Duloxetine treatment in two months. Daily drug intake will be one capsule that will receive a capsule of 20 mg in the first month and a 30 mg capsule in the

second month. The capsules without the knowledge of the patient and the examiner will be given to patients with any drug-related code in a questionnaire elderly patient.

**Category**

Treatment - Drugs

**2****Description**

Control group: The control group will receive placebo treatment in two months. Placebo capsules (lactose powder, gelatin solution, 5% and MCC) in terms of shape, size, color and smell are similar to capsules Duloxetine .

**Category**

Placebo

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

Farabi Hospital

**Full name of responsible person**

Faezeh Tatari

**Street address**

Farabi Hospital, Isar square

**City**

Kermanshah

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6713567909

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s\_salemi85@yahoo.com

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Korosh Hamzehee

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah

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khamzehee@kums.ac.ir

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

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Faezeh Tatari

**Position**

Psychiatrist

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Farabi Hospital, Isar square

**City**

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**Province**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Faezeh Tatari

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Faezeh Tatari  
**Position**  
Psychiatrics  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is 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

### Title and more details about the data/document

I have no plans at this time

### When the data will become available and for how long

I have no plans at this time

### To whom data/document is available

I have no plans at this time

### Under which criteria data/document could be used

I have no plans at this time

### From where data/document is obtainable

I have no plans at this time

### What processes are involved for a request to access data/document

I have no plans at this time

### Comments