Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy of duloxetinein 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)

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+98 83 3821 1001

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

Public title
Compareing effects of duloxetinein 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Faezeh Tatari

Position

Associate Professor

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Other areas of specialty/work

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Person responsible for updating data

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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