

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The efficacy of venlafaxine 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 efficacy of venlafaxine in the treatment of depression, withdrawal symptoms, craving for methamphetamine compared to placebo (clinical trial with a 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

Intervention group: Intervention group: The group will receive venlafaxine 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. 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 venlafaxine .

Main outcome variables

Depression, withdrawal signs, craving

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160717028967N8**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **prospective**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

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 venlafaxine in the treatment of

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

Public title

Comparing effects of venlafaxine 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:

Gender female No use of other drugs and stimulants at the time of entering the study The absence of comorbid psychiatric disorders symptoms

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

Simple randomization

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

2018-01-31, 1396/11/11

Ethics committee reference number

kums.rec.1396.595

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F15

ICD-10 code description

Mental and behavioral disorders due to use of other stimulants, including caffeine: dependence syndromes

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: The group will receive duloxetine treatment in two months

Category

Treatment - Drugs

2

Description

Control group: The control group will receive placebo treatment in two months

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

Korosh Hamzehee

Street address

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

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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

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Faezeh Tatari

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Associate Professor

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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

Psychiatrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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