Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of Trimipramine in reducing the temptation and rate of relapse of methamphetamine use compared with placebo (clinical trial with a control group)

Protocol summary

Study aim
Evaluation of the effect of Trimipramine in reducing the temptation and rate of relapse of methamphetamine use compared with placebo (clinical trial with a control group)

Design
Clinical trials with control group, parallel groups, double blind, randomized

Settings and conduct
This study is a double blind trial. The study sample population is consist of all Methamphetamine dependent referring to Farabi Hospital in Kermanshah, that 132 persons will selected in available method and randomly will be divided into two groups. In the experimental group, the participants will receive daily two pills of Trimipramine, while the control group two placebo pills daily. All subjects in all two groups will be re-evaluated by completing questionnaires at baseline, 4 weeks and at the end of the study (8 weeks after baseline), their temptation and relapse will be assessed again.

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 and also, Patients who did not agree to participate in the study, were excluded

Intervention groups
Intervention group: The group will receive Trimipramine treatment in two months. The daily dose will be two pills that the person will receive 75 mg in the first month and 150 mg in the second month. The control group will receive placebo treatment in two months. Daily placebo intake will be two pills. Placebo pills (lactose powder, gelatin solution, 5% and Vocel) in terms of shape, size, color and smell are similar to the Trimipramine pills.

Main outcome variables
temptation and relapse

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150822023705N12**
Registration date: **2019-09-03, 1398/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-03, 1398/06/12**
Update count: **0**

Registration date
2019-09-03, 1398/06/12

Registrant information

Name
Mostafa Alikhani

Name of organization / entity
Kermanshah University of Medical Sciences - Substance Abuse Prevention Research Center

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-06, 1398/04/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Trimipramine in reducing the temptation and rate of relapse of methamphetamine use compared with placebo (clinical trial with a control group)

Public title

Compareing effects of Trimipramine and Placebo on temptation and rate of relapse

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:

Disagreement to participate in the study

Age

No age limit

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two equal groups (A and B) based on a randomized six-block table designed using Random allocation software. In order to randomly assign 132 patients to the intervention and control groups, six different blocks of 22 different letters A and B, which indicate the terminals of the trimimipermin and placebo groups, are initially created. These blocks are then numbered from one to six. In the next step, each of these blocks is randomly selected by performing 6 drawings from numbers 1 to 6 each. Thus, in each lottery, by selecting a block, a combination of 22 letters of the letters A (trimimipermin group) and B (placebo group) is obtained. At the end of the 6 drawings, after selecting 6 blocks, a total of 132 The letters A and B will be obtained. The resulting combination of letters A and B is single, and are placed in 132 separate and sealed envelopes, respectively. following each patient recourse an envelope is opened to determine the group of that patient.

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

2019-05-08, 1398/02/18

Ethics committee reference number

IR.KUMS.REC.1398.144

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

temptation

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

Temptation Questionnaire

2

Description

relapse

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

Relapse Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will receive Trimipramine treatment in two months. The daily dose will be two pills that the person will receive 75 mg in the first month and 150 mg in the second month. These pills will be given to patients without knowledge of the patient and the examiner, and the code for each drug will be recorded in the patient's questionnaire. Trimipramine will be purchased from Tehran Chemistry Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive placebo treatment in two months. Daily drug intake will be two pills. Placebo pills (lactose powder, gelatin solution, 5% and Vocel) in terms of shape, size, color and smell are similar to the Trimipramine pills. The placebo will be provided by the Kermanshah Pharmaceutical Faculty.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Payam Mohammadi

Street address

Isar square, Farabi Hospital

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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?

No

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

Hossein Ramyar

Position

Assistant Psychiatrist

Latest degree

Medical doctor

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