Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The efficacy of Omega-3 Fatty Acids Supplement in the treatment Patients with Methamphetamine-Induced Mood Disorder compared with placebo in amphetamine Users (clinical trial with a control group)

Protocol summary

Study aim
Evaluation of the effect of omega-3 fatty acids supplements in the treatment of patients with methamphetamine-Induced mood disorder compared with placebo (clinical trial with a control group)

Design
Clinical trials with control group, parallel groups, double-blind, randomized, phase 3, 50 patients

Settings and conduct
This study is a double-blind trial. The study sample population is consists of all Patients with Methamphetamine-Induced Mood Disorder referring to Farabi Hospital in Kermanshah, that 50 persons will be selected in the available method and randomly will be divided into two groups. In the experimental group, the participants will receive daily 1 capsule of 1000 mg of Omega-3, while the control group 1 capsule of 1000 mg of Placebo daily. All subjects in all two groups will be re-evaluated by completing questionnaires at baseline, 4 weeks and the end of the study (8 weeks after baseline), will be assessed.

Participants/Inclusion and exclusion criteria
Both genders; Methamphetamine-Induced Mood Disorder diagnosed according to Diagnostic and Statistical Manual of Mental Disorders fifth edition by a psychiatrist; Methamphetamine dependence diagnoses accordingly Diagnostic and Statistical Manual of Mental Disorders fifth edition and TLC test; The dominant use of methamphetamine for at least 6 months, lack of serious psychiatric disorders. Patients who are not agree to participate in the study will be excluded.

Intervention groups
The group will receive Omega-3 treatment in two months. The daily dose will be 1 capsule of 1000 mg. The control group will receive placebo treatment in two months. Daily drug intake will be 1 capsule of 1000 mg. Placebo capsules in terms of shape, size, color, and smell are similar to the Omega-3 capsules

Main outcome variables
relapse, cravings, withdrawal symptoms, depression, mania, anxiety, sleep quality, sexual function, and emotion regulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150822023705N13**
Registration date: **2020-11-23, 1399/09/03**
Registration timing: **prospective**

Last update: **2020-11-23, 1399/09/03**
Update count: **0**

Registration date
2020-11-23, 1399/09/03

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
2020-12-25, 1399/10/05

Expected recruitment end date
2021-08-27, 1400/06/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The efficacy of Omega-3 Fatty Acids Supplement in the treatment Patients with Methamphetamine-Induced Mood Disorder compared with placebo in amphetamine Users (clinical trial with a control group)

Public title
Comparing the effects of Omega-3 Fatty Acids Supplement and Placebo in the treatment Patients with Methamphetamine-Induced Mood Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Methamphetamine dependence diagnoses according to Diagnostic and Statistical Manual of Mental Disorders fifth edition and TLC test Methamphetamine-Induced Mood Disorder diagnoses accordingly Diagnostic and Statistical Manual of Mental Disorders fifth edition by a psychiatrist 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
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two equal groups (A and B) based on a randomized ten-block design using random allocation software. To randomly assign 50 patients to the intervention and control groups, five different blocks of 10 different letters A and B, which indicate Omega-3 Fatty Acids Supplement and placebo groups respectively, will be initially created. These blocks then will be numbered from one to ten. In the next step, each of these blocks will be randomly selected by performing lottery using 10 card with letters from 1 to 10 on them. Thus, in each lottery, by selecting a block, a combination of 5 letters of the letters A (Omega-3 Fatty Acids Supplement group) and B (placebo group) will be obtained. At the end of the 10 drawings, after selecting 10 blocks, a total of 50 letters A and B will be obtained. The resulting combination of letters A and B is single, and will be placed in 50 separate and sealed envelopes, respectively. following each patient recourse, an envelope will be 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 name of the medication. The doctor is also unaware of the type of drug used in each group. The color and smell of the 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
Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Approval date
2020-11-10, 1399/08/20
Ethics committee reference number
IR.KUMS.REC.1399.808

Health conditions studied

1

Description of health condition studied
Methamphetamine-Induced Mood Disorder
ICD-10 code
F15.94
ICD-10 code description
Other stimulant use, unspecified with stimulant-induced mood disorder

Primary outcomes

1

Description
relapse
Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

relapse Questionnaire

2

Description

craving

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

craving Questionnaire

3

Description

withdrawal symptoms

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

withdrawal symptoms Questionnaire

4

Description

depression

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

depression Questionnaire

5

Description

mania

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

mania Questionnaire

6

Description

anxiety

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

anxiety Questionnaire

7

Description

sleep quality

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

sleep quality Questionnaire

8

Description

sexual function

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

sexual function Questionnaire

9

Description

emotion regulation

Timepoint

before intervention- 4 weeks later- 8 weeks later

Method of measurement

emotion regulation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will receive Omega-3 Fatty Acids Supplement treatment in two months. The daily dose will be 1 capsule of 1000 mg. These capsules will be given to patients without awareness of the patient and the examiner, and the code for each drug will be recorded in the patient's questionnaire. Omega-3 Fatty Acids Supplement will be purchased from Adonis Kish Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive placebo treatment in two months. Daily drug intake will be 1 capsule of 1000 mg. Placebo capsules in terms of shape, size, color and smell are similar to the Omega-3 Fatty Acids Supplement capsules.

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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Province

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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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
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Position
Assistant Psychiatrist
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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