

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 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 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)

Phone

+98 838264513

Email address

mo.alikhani@kums.ac.ir

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
City
Kermanshah
Province
Kermanshah
Postal code
6719851115
Phone
+98 83 3827 6683

Email

payam.mohammadi@yahoo.com

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

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Phone

+98 83 3836 0014

Email

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

Nona Vaezi

Position

Assistant Psychiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Isar square, Farabi Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Phone

+98 83 3826 4513

Email

Amirvaezi007@yahoo.com

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

Kermanshah University of Medical Sciences

Full name of responsible person

Faeze Tatari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Isar square, Farabi Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Phone

+98 83 3826 4513

Email

fztatari37@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Mostafa Alikhani

Position

Research Assistant

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Isar square, Farabi Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Phone

+98 83 3826 4513

Email

m.alikhani18@yahoo.com

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