

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effectiveness of omega-3 fatty acid supplementation compared with placebo in the treatment of patients with mood disorders caused by methamphetamine

Protocol summary

Study aim

Study of the effectiveness of omega-3 fatty acid supplementation compared with placebo in the treatment of patients with mood disorders caused by methamphetamine

Design

In this double-blind clinical trial with parallel groups (intervention and a control) the researcher and the patients will be aware of participation in the study and probability of receiving a new medication but the researcher and the participant will be kept blinded about allocation to each group. In this phase 2-3 randomized study, at least 50 patients with mood disorders will participate. A random number table will be used for randomization.

Settings and conduct

This double-blind study will be conducted in Farabi hospital, Kermanshah. TLC test will be performed to confirm methamphetamine use, and based on a structured DSM-VI interview, a psychiatrist must confirm the diagnosis of methamphetamine-induced mood disorder.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of methamphetamine-induced mood disorders based on DSM5 diagnostic criteria. Exclusion criteria: Simultaneous use of other substances; History of primary mood disorders; History of brain disorders; People with certain diseases and kidney patients; People with blood clotting problems

Intervention groups

Intervention group: In addition to standard treatment, the intervention group will receive 30 capsules containing 1 gram of omega-3 for 8 weeks (1 capsule daily). Control group: In addition to standard treatment, the control group will receive 30 capsules containing 1 gram of placebo for 8 weeks (1 capsule daily).

Main outcome variables

Recurrence rate; Temptation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N161**

Registration date: **2021-03-08, 1399/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-08, 1399/12/18**

Update count: **0**

Registration date

2021-03-08, 1399/12/18

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of omega-3 fatty acid supplementation compared with placebo in the treatment of patients with mood disorders caused by methamphetamine

Public title
The effect of omega-3 fatty acids in the treatment of patients with mood disorders caused by methamphetamine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of methamphetamine-induced mood disorders based on DSM5 diagnostic criteria
Exclusion criteria:
Simultaneous use of other substances History of primary mood disorders History of brain disorders People with certain diseases and kidney patients People with blood clotting problems

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients will be divided into two groups of 25. Each patient will be assigned a 4-digit code based on the random number table, Based on the right number of patients' code, the patients will be divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blinded study, the researcher and the patient do not know who will receive the new drug. Patients will be aware of the participation in the study, but the researcher and the participant will be kept blinded to which group will receive the new medicine and which group will receive the placebo. The placebo and the new drug are both in the same capsule form, kept in the same container. Drugs can only be identified by the serial number on the container.

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
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141

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
Mood disorders

ICD-10 code
F31.32

ICD-10 code description
Bipolar disorder, current episode depressed, moderate

2

Description of health condition studied
Methamphetamine Dependency

ICD-10 code
F15.15

ICD-10 code description
Other stimulant abuse with stimulant-induced psychotic disorder

Primary outcomes

1

Description
Recurrence rate

Timepoint
Beginning of the study, end of the fourth week, end of the eighth week

Method of measurement

Based on recurrence questionnaire (RPS)

2

Description

Temptation

Timepoint

Beginning of the study, end of the fourth week, end of the eighth week

Method of measurement

Based on the temptation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, in addition to standard treatment, will receive 30 capsules containing 1 gram of omega-3 for 8 weeks (1 capsule daily).

Category

Treatment - Drugs

2

Description

The control group, in addition to standard treatment, will receive 30 capsules containing 1 gram of placebo for 8 weeks (1 capsule daily).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Dr. Faezeh Tatari

Street address

Isar Square, Dolatabad Boulevard, 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

Dr. Reza Khodarahmi

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

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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

Nona Vaezi

Position

Resident of psychiatric

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Faezeh Tatari

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Latest degree

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available