

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparing efficacy of Omega-3 and placebo in reducing beck depression score in HIV/AIDS patients

Protocol summary

Summary

The goal of this study is comparing efficacy of Omega-3 and placebo in reducing depression beck score in HIV/AIDS patients. This study is a randomized, double-blind clinical trial. One-hundred HIV positive patients, received antiretroviral therapy for at least one year and CD4 count \geq 350, with beck depression score \geq 16 will be included. Based on the block randomization method, included patients will be recruited in two equal groups. First group will be received soft gelatin Cap of omega-3, 1000 mg twice daily, for 8 weeks. The second group will be received placebo Cap, 1000 mg twice daily, for 8 weeks. Patients with history of other psychological disorders, major depression with recent suicidal attempt, history of drugs or alcohol abuse, sensitivity to omega-3, coagulation disorders or intake of anticoagulants and receiving any drugs that affect patients' mood including anti-depressants will be excluded. The patients will be visited at time of entrance to the study and weeks 4 and 8. All patients will complete beck depression questionnaire at these times. Finally changes in the beck depression scores will be compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410073449N17**

Registration date: **2014-10-19, 1393/07/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-19, 1393/07/27

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4715

Email address

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Recruitment status

Recruitment complete

Funding source

Research grant from Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy of Omega-3 and placebo in reducing beck depression score in HIV/AIDS patients

Public title

Effect of Omega-3 on depression of HIV/AIDS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: HIV positive patients with age between 18-65 years old, received antiretroviral therapy for at least one years, CD4 count \geq 350 and Beck Depression Score (BDS) \geq 16. Exclusion criteria: HIV positive patients suffering from other psychological disorders, major depression with recent suicidal attempt, history of drugs

or alcohol abuse, other concomitant severe medical diseases such as diabetes mellitus, intake of omega-3 during last 3 months, sensitivity to omega-3, coagulation disorders or intake of anticoagulants and receiving any drugs that affect patients' mood including anti-depressants.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Included patients will be assigned to the Omega-3 or Placebo group based on the block randomization method. Randomization and distribution of the omega-3 or placebo will be done by the hospital pharmacy department and researchers, physicians and patients will be blinded regarding type of intervention (Omega-3 or placebo).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods Ave.

City

Tehran

Postal code**Approval date**

2014-04-29, 1393/02/09

Ethics committee reference number

93-02-33-25813

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F32

ICD-10 code description

In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity.

Primary outcomes**1****Description**

Beck depression score

Timepoint

at baseline, weeks 4 and 8.

Method of measurement

Beck Depression Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Soft gelatin Cap of omega-3 (Cap 1000 mg, Zahravi Pharmaceutical Company, Tabriz, Iran), One Cap orally twice daily, for 8 weeks

Category

Treatment - Drugs

2**Description**

Soft gelatin Cap of Placebo (Cap 1000mg, Zahravi Pharmaceutical Company, Tabriz, Iran), One Cap orally twice daily, for 8 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Hossein Khalili

Street address

Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of
Medical Sciences

Full name of responsible person

Masoud Yunesian

Street address

Ghods Ave.

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Pharm. D

Other areas of specialty/work

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty