Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy of eicosapentaenoic acid in patients with chronic migraine headache; a randomized controlled trial

Protocol summary

Study aim
Determining the anti-migraine effects of eicosapentaenoic acid in controlling migraine symptoms.

Design
Single-center, randomized, three-blind, phase three clinical trials of 60 patients with chronic migraine in equal numbers were assigned to two groups of eicosapentaenoic acid, placebo.

Settings and conduct
Patients' follow-up evaluators, statistical data analysts, and quality controllers are blinded. Executors of the interventions are excluded from this study and are prescribed based on the codes provided in sealed packages.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1) Patients with chronic migraine based on ICHD-3 criteria 2) Age between 18 to 50 years 3) Signing a written consent Exclusion Criteria: 1) Any contraindications to use EPA, such as history of hypersensitivity reactions 2) Pregnancy 3) Nursing Mothers 4) Patients treated with antiplatelet or anticoagulant drugs. 5) Patients with a history of bleeding disorders.

Intervention groups
Patients in this study will be randomly divided into two groups, the intervention group will receive 2000 mg per day orally EPA and the control group, which will receive a placebo that is very similar in appearance and packaging to the drug sample.

Main outcome variables
The main outcome is the HIT-6 index and the secondary outcomes include 1) a questionnaire to assess pain during the day 3) a quality of life questionnaire.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20170608034390N9**
Registration date: **2022-05-11, 1401/02/21**
Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**
Update count: **0**

Registration date
2022-05-11, 1401/02/21

Registrant information

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Name of organization / entity
SBMU
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2023-05-22, 1402/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of eicosapentaenoic acid in patients with chronic migraine headache; a randomized controlled trial

Public title
evaluation of the efficacy of eicosapentaenoic acid in patients with chronic migraine headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic migraine based on the ICHD-3 criteria Ages between 18 and 50 Provide written consent
Exclusion criteria:
Contraindications to EPA such as allergies Patients with a history of bleeding disorders Patients with increased risk of bleeding Pregnant patients Lactating patients Patients treated with antiplatelet or anticoagulant drugs
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After preparing the medicine and placebo, they will be packed in the same box by a clinical laboratory expert who is outside the researchers and the randomization code will be provided to them based on the Excel file extracted from Sealed Envelope software. The package will be transferred to the clinic and the codes will remain closed until the statistical analysis is performed. In this case, the present study will be a blind three-way study.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Researchers included in the study, including the physician who examines patient eligibility, the physician who examines the response to interventions, the statistical analyst of data, and the controller of study quality, are all blinded, but due to the different nature of interventions, the possibility of blinding There is no executor, so a sealed envelope containing the patient treatment code was sent to the relevant prescriber or neurologist who only performed the interventions and did not play a role in follow-up in the patients' eligibility review, treatment and outcome measurement processes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of
Street address
Central department of ministry of health and medical education, Simaye Iran st, Shahrak Ghods
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2021-09-25, 1400/07/03
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.149

Health conditions studied

1

Description of health condition studied
Chronic migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache impact test 6 (HIT-6)
Timepoint
The frequency, severity and duration of headaches are measured monthly for two months.
Method of measurement
Headache impact test 6 (HIT-6)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive 2000 mg of EPA daily in the form of add on treatment, products are softgels containing 1000 mg of EPA-ethyl ester (EPA-EE) made by Yas Kavir Pharmaceutical Company in accordance to

good manufacturing practice of pharmaceutical production and the placebo will contain 1000 mg of edible oil with the same shape, smell, taste and color. In both groups, patients will consume one soft gel twice a day after meals for 8 weeks.

Category

Treatment - Other

2

Description

Control group: first-line anti-migraine prophylactic agent and placebo soft gel(apparently similar with the EPA soft gels)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Hadi Esmaily

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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5th floor, 2nd construction, Aarabi avenue, Velenjak, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hadi Esmaily

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Potentially the whole data is published after participants become unidentified.
When the data will become available and for how long
The access Starts in 6 months period after publishing of the results
To whom data/document is available
Researchers working in academic and industrial institutions.
Under which criteria data/document could be used
t can be used to carry out research work.
From where data/document is obtainable
Dr. Hadi Esmaily, Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences.
What processes are involved for a request to access data/document
It will be available with sending a request by email to corresponding author (Esmaily_hadi@sbmu.ac.ir).
Comments