

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluating the efficacy of eicosapentaenoic acid in patients with acute respiratory distress syndrome: A Randomized Controlled Trial.

Protocol summary

Study aim

Determining the efficacy of eicosapentaenoic acid on the respiratory parameters in patients with acute respiratory distress syndrome

Design

A clinical trial with a control group, with a parallel group, blinded and randomized, includes 80 patients in two groups.

Settings and conduct

This study will be a blinded clinical trial conducted on patients with acute respiratory distress syndrome admitted to Imam Hossein Hospital. The drug and placebo are completely similar in appearance, so all participants in the study will be blinded to the groups, and a block method will be used for randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients older than 18 years; with mild to moderate acute respiratory distress syndrome, PaO₂/FiO₂ between 100 and 300 mmHg, bilateral pulmonary infiltration and receiving mechanical ventilation. Exclusion criteria: hypersensitivity to any components of the product, pregnancy, platelet count below 50,000/ μ l, patients with increased risk of bleeding, hepatic insufficiency.

Intervention groups

Patients will be randomly divided into two equal groups. The intervention group will receive 6 grams of eicosapentaenoic acid per day, and the control group will receive a placebo that is completely identical in appearance to the drug sample.

Main outcome variables

The main outcome is ratio of arterial partial pressure of oxygen (Pao₂) to the fraction of inspired oxygen (FiO₂) and the secondary outcomes include duration of mechanical ventilation, ICU length of stay, organ failure assessment and changes in oxygenation and breathing pattern.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170608034390N18**

Registration date: **2025-05-25, 1404/03/04**

Registration timing: **prospective**

Last update: **2025-05-25, 1404/03/04**

Update count: **0**

Registration date

2025-05-25, 1404/03/04

Registrant information

Name

Hadi Esmaily

Name of organization / entity

SBMU

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-10, 1404/03/20

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of eicosapentaenoic acid in patients with acute respiratory distress syndrome: A Randomized Controlled Trial.

Public title

Evaluating the efficacy of eicosapentaenoic acid in patients with acute respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Mild to moderate acute respiratory distress syndrome (ARDS) with PaO₂/FiO₂ between 100 and 300 mmHg
Adult Patients (older than 18 years) Receiving mechanical ventilation Bilateral pulmonary infiltration

Exclusion criteria:

Hypersensitivity to any component of the product
Pregnancy Platelet count below 50,000/ μ l Patients with increased risk of bleeding Hepatic insufficiency

Age

From **18 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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

We will randomly divide the participants into two groups of the same size of 40 participants (80 patients in total), to ensure the same distribution of volunteers in the two groups, the block randomization method will be used. 10 blocks, each block including 8 participants randomly and equally distributed in each block, will be used for randomization using the block randomization service of the online software www.sealedenvelope.com.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, healthcare providers, investigator, outcome assessors and data analyst and quality controller are all blinded. The preparation of the drug or placebo inside the syringe will be done by a clean room expert in the hospital who is not part of the research team, and based on the block randomization table, the syringes will be prepared and delivered to the researchers with a unique code.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Pharmacy Faculty, Shahid Beheshti University of Medical Sciences

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No.2660, Pharmacy Faculty, Shahid Beheshti University of Medical Sciences, Valiasr street

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2024-10-28, 1403/08/07

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1403.154

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

Acute respiratory distress syndrome

ICD-10 code

J80

ICD-10 code description

Acute respiratory distress syndrome

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

Ratio of arterial partial pressure of oxygen (Pao₂) to the fraction of inspired oxygen (FiO₂)

Timepoint

Before intervention and 4 and 7 days after intervention

Method of measurement

Arterial Blood Gas (ABG) test

Secondary outcomes**1****Description**

Duration of mechanical ventilation (days)

Timepoint

Before intervention and at the time of extubation

Method of measurement

Observation

2

Description

ICU length of stay (days)

Timepoint

Before intervention and at the end of an ICU admission

Method of measurement

Observation

3

Description

Organ Failure Assessment

Timepoint

Before intervention and 4 and 7 days after intervention

Method of measurement

Evaluation of various parameters such as clinical and blood serum factors

4

Description

Changes in oxygenation and breathing pattern

Timepoint

Before intervention and 4 and 7 days after intervention

Method of measurement

Ventilator-derived parameters

Intervention groups

1

Description

Intervention group: The intervention group will receive 6 grams of eicosapentaenoic acid daily for 1 week as an add-on treatment.

Category

Treatment - Other

2

Description

Control group: In this group, 6 grams of corn oil is administered daily as placebo for 1 week with the same appearance and organoleptic condition.

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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Shahid Madani Street, Tehran, Iran

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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

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Person responsible for updating data

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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 will be published after participants become unidentified.

When the data will become available and for how long

The data will be available 6 months after data publication.

To whom data/document is available

Researchers working in academic and industrial institutions.

Under which criteria data/document could be used

It can be used to carry out research work.

From where data/document is obtainable

Dr. Hadi Esmaeili, 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