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/µl, 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)
Phone
+98 21 8887 3704
Email address
esmaily_hadi@sbmu.ac.ir

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/µl 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
Street address
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
Street address
Shahid Madani Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
Email
info@ehmc.ir
Web page address
https://www.ehmc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
5th floor, 2nd construction, Aarabi avenue, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
info@sbmu.ac.ir
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

Street address
Shahid Beheshti Pharmaceutical Faculty, Vali Asr Ave.

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 8820 0118

Email
Esmaily_hadi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hadi Esmaily

Position
Assistant Professor

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Other areas of specialty/work
Medical Pharmacy

Street address
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Tehran

Postal code
1991953381

Phone
+98 21 8820 0118

Fax

Email
Esmaily_hadi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hadi Esmaily

Position
Assistant Professor

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Province
Tehran

Postal code
1991953381

Phone
+98 21 8820 0118

Fax

Email
Esmaily_hadi@sbmu.ac.ir

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