

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of addition of omega-3 fatty acids on the standard treatment of critical ill patients with acute lung injury on mortality rate compared to standard treatment in intensive care unit

Protocol summary

Summary

The objective of this study is to evaluate the effect of omega-3 fatty acids therapy on treatment of acute lung injury (ALI). After obtaining approval from the university ethics committee, 58 patients with ALI admitted in ICU will be enrolled in this study. Written consent will be obtained from all patients or their guardians. Patients with ALI will be defined as those with $Pao_2/Fio_2 < 250$, and lung injury whose diagnoses have been made within less than 48 hours. Patients will be randomly assigned to two groups (block randomization). In first group, patients will receive standard treatment with omega 3 capsules gavage, 6 capsules daily (2 capsules TDS) for 14 days. In second group patients will receive standard treatment. On admission and, seventh and fourteenth days, oxygenation, lung mechanics and inflammatory factors, ventilator free days, number of organ failure and neutrophil peroxidation activity will be measured and evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020612387N1**

Registration date: **2013-08-28, 1392/06/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-28, 1392/06/06

Registrant information

Name

Farnaz Valiei

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of addition of omega-3 fatty acids on the standard treatment of critical ill patients with acute lung injury on mortality rate compared to standard treatment in intensive care unit

Public title

The effect of omega-3 fatty acids on the treatment of acute lung injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with ALI criteria ($Pao_2/Fio_2 < 250$ and lung injury), less than 48 hours from their diagnosis. Exclusion criteria: Patients <18 years old,

patients' or their guardians' unwillingness to participate, HIV, plasma TG >400, renal or liver failure, history of frequent transfusions, Thrombocytopenia (PLT<80000), Leukopenia (WBC<3000).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This is a single-blind study. Patients are blinded to the intervention.

Secondary Ids

empty

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

Tabriz Medical University ethics committee

Street address

Golgasht St.

City

Tabriz

Postal code

5167717289

Approval date

2012-10-29, 1391/08/08

Ethics committee reference number

91150

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

Acute lung injury

ICD-10 code

J96.0

ICD-10 code description

Acute respiratory failure

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

Pao2/Fio2

Timepoint

On admission, seventh and fourteenth days

Method of measurement

Oxygenation, lung mechanic and inflammatory factors

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

Ventilator free days

Timepoint

On admission, seventh and fourteenth days

Method of measurement

Air way compliance and resistance is recorded.

2**Description**

Neutrophil peroxidation activity

Timepoint

On admission, seventh and fourteenth days

Method of measurement

After performing Mini- BAL, the fluid will be centrifuged and the debris will be removed. To measure the activity of neutrophil peroxidation, a marker of lung injury, the fluid will be sent to the laboratory.

3**Description**

Number of organ failure

Timepoint

On admission, seventh and fourteenth days

Method of measurement

Evaluation of various parameters such as clinical and blood serum factors.

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

Intervention group: Standard treatment with omega 3 capsules gavage, 6 capsules daily (2 capsules TDS) for 14 days.

Category

Treatment - Drugs

2**Description**

Control group: ALI standard treatment (low tidal volume strategy, VT:6 ml/kg)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
General ICU of Shohada Hospital
Full name of responsible person
Street address
El-goli St.
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
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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
Vice chancellor for Research, Tabriz 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

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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