Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of omega-3 clinical trial in the prevention of delirium in hospitalized patients in intensive care unit

Protocol summary

Summary

Background: In this study the effect of omega-3 in the prevention of delirium will be studied. Methods: This study is a double blind randomized clinical trial that will be done on patients connected to the ventilator. Patients will be divided into two groups. Patients who are in the drug group will be gavage with 2 grams of omega-3 daily. In the second group will be gavage placebo. Patient medications are withheld when patients are discharged from ICU or pass 7 days of ICU admitted or Patients do not have delirium basis of Confusion assessment method for the ICU criteria two consecutive days. Primary outcomes included number of days without delirium during the first 7 days of hospitalization. Secondary outcomes included mortality during hospitalization in ICU, The number of days that patients are not connected to ventilator in the ICU stay, the number of ICU days stay. The variables collected will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509055363N5**
Registration date: **2015-11-20, 1394/08/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-20, 1394/08/29

Registrant information

Name

Taraneh Naghibi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 clinical trial in the prevention of delirium in hospitalized patients in intensive care unit

Public title

The effect of omega-3 in the prevention of delirium in intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: APACHEE score under 25; GCS=7-9; age over 18 years; Patients under mechanical ventilation; No history of dementia-Alzheimer and Parkinson; No use of anti-psychotic drugs; No history of allergy to omega-3 or fish; Patients who are not suffering from brain damage; Patients who were admitted due to surgical complications in the intensive care unit
Exclusion criteria: Separated from the ventilator in less than 72 hours; Death in less than 48 hours; Discharge

from the ICU in under 72 hours

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

Vice- Chancellor for Research, Zanjan University of Medical Sciences, Azadi Blvd, Zanjan

City

Zanjan

Postal code

Approval date

2015-09-02, 1394/06/11

Ethics committee reference number

ZUMS.REC.1394.165

Health conditions studied

1

Description of health condition studied

delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium

Primary outcomes

1

Description

number of days without delirium during the first 7 days of hospitalization

Timepoint

Twice daily

Method of measurement

CAM-ICU: Confusion assestment method for the ICU

Secondary outcomes

1

Description

mortality during hospitalization in ICU

Timepoint

End of the study

Method of measurement

Records

2

Description

The number of days that patients are not connected to ventilator in the ICU stay

Timepoint

End of the study

Method of measurement

Records

3

Description

the number of ICU days stay

Timepoint

End of the study

Method of measurement

Records

Intervention groups

1

Description

Patients who are in the drug group will be gavage with 2 grams of omega-3 daily.

Category

Treatment - Drugs

2

Description

In the control group placebo (syrup, methyl cellulose) will be gavage.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mosavi Hospital

Full name of responsible person
Dr Taraneh Naghibi
Street address
Mosavi Hospital, Gavazang Blvd, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice- Chancellor for Research of Zanjan University
Full name of responsible person
Dr Faghihzadeh
Street address
Office of Vice- Chancellor for Research, Zanjan University of Medical Sciences
City
Zanjan
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 of Zanjan University
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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Person responsible for updating data

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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