

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 gavaged with 2 grams of omega-3 daily. In the second group will be gavaged 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

+98 24 3347 2865

Email address

tnaghibi@zums.ac.ir

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

City

Zanjan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice- Chancellor for Research of Zanjan University

Full name of responsible person

Dr Faghihzadeh

Street addressOffice 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****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Navid Shafigh

Position

Resident of Anesthesiology

Other areas of specialty/work**Street address**

Mosavi Hospital, Gavazang Blvd, Zanjan

City

Zanjan

Postal code**Phone**

+98 24 3347 2865

Fax**Email**

Navid_shafigh2005@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Taraneh Naghibi

Position

ICU Fellowship- Assistant Professor

Other areas of specialty/work**Street address**

Mosavi Hospital, Gavazang Blvd, Zanjan

City

Zanjan

Postal code**Phone**

+98 24 3347 2865

Fax**Email**

tnaghibi@zums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Faramarz Dobakhti

Position

Associated

Other areas of specialty/work**Street address**Faculty of pharmacy, Zanjan University of Medical
Sciences**City**

Zanjan

Postal code**Phone**

+98 24 3347 2865

Fax**Email****Web page address****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*