

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The Effect of Omega-3 prescription on serum levels of Interleukin-6 and Interleukin-1 beta in patients with traumatic brain injury

Protocol summary

Study aim

survey the effect of Omega-3 prescription on serum levels of Interleukin-6 and Interleukin-1 beta in patients with traumatic brain injury

Design

In a randomized double-blind phase 3 clinical trial study, 80 patients were randomly divided into two groups of 40 patients who receiving omega-3 and placebo capsule every night for 7 days. then On the seventh day, Glasgow Coma Scale and serum levels of IL-6 and IL-1 beta will be measured in two groups

Settings and conduct

80 patients with traumatic brain injury referred to Ahvaz Imam Khomeini Hospital were divided into two groups receiving oral omega-3 capsules and placebo capsule recipients but this capsule encoded and patient and the person who evaluating patient don't know the kind of drug. after 7 days Glasgow Coma Scale and serum levels of IL-6 and IL-1 beta will be measured in two groups

Participants/Inclusion and exclusion criteria

inclusion criteria is Patients with traumatic brain injury and exclusion criteria is history of seafood susceptibility, history of severe and uncontrollable hypertension, consumption of immunosuppression, consumption of antiepileptic, liver dysfunction and Kidney disorder

Intervention groups

Oral Omega-3 capsule recipient group
normal saline placebo capsule recipient group

Main outcome variables

Glasgow Coma Scale, serum levels of IL-6 and IL-1 beta

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180223038838N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Fereshteh Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 8989

Email address

amiri.fe@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2018-09-11, 1397/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Omega-3 prescription on serum levels of Interleukin-6 and Interleukin-1 beta in patients with traumatic brain injury

Public title

The Effect of Omega-3 prescription on serum levels of Interleukin-6 and Interleukin-1 beta in patients with traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with traumatic brain injur

Exclusion criteria:

History of seafood susceptibility History of severe and uncontrollable hypertension Consumption of immunosuppression Consumption of antiepileptic Liver Dysfunction Kidney disorder

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Use of the same coded capsule and then patients and the clinical elevators do not know the kind of drug

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapour University of Medical Sciences

Street address

Ahvaz Jundishapour University of Medical Sciences, Golestan blv, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-27, 1396/11/07

Ethics committee reference number

IR.AJUMS.REC.1396.926

Health conditions studied

1

Description of health condition studied

traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Glasgow Coma Scale

Timepoint

Before the intervention and seven days after the intervention

Method of measurement

Glasgow coma scale score

2

Description

Serum level of interleukin-6

Timepoint

Before the intervention and seven days after the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

3

Description

Serum level of interleukin-1 beta

Timepoint

Before the intervention and seven days after the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipient of oral Omega 3 capsule

Category

Treatment - Drugs

2

Description

Control group: Recipient of oral placebo capsule

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Dr Fereshteh Amiri

Street address

Ahvaz Golestan hospital, Golestan blv, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badavi

Street address

Vice Chancellor for Research, Ahvaz Jundishapour
University of Medical Sciences, Golestan BLV, Ahvaz,
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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Fereshteh Amiri

Position

Phycision

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Not applicable

Title and more details about the data/document

all documents

When the data will become available and for how long

Unlimited

To whom data/document is available

all readers

Under which criteria data/document could be used

without any criteria

From where data/document is obtainable

Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences

What processes are involved for a request to access data/document

it is belong to Vice Chancellor for Research, Ahvaz
Jundishapur University of Medical Sciences

Comments