Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Omega-3 supplementation on immune responses in elite paddlers

Protocol summary

Summary

Objectives: An investigation of the immunomudulatory effects of intensive exercise and fish-oil supplement in elite paddlers. Design: A randomized double blind placebo-controlled, phase II design will be used for this study. Setting and conduct: The study will be performed in department of Immunology, School of Public Health, Tehran University of Medical Sciences. Participants: Twenty two elite competitive paddlers, all from the Iranian national dragon butt team will participate in our study. The main inclusion criteria: 18 to 30 years of age, non-smoking, agree to avoid sea foods throughout the study,sign informed consent. The main exclusion criteria: History of cardiovascular disease or diabetes, allergy to fish oil, appearance of intestinal side effects such as chronic and acute abdominal pains, diarrhea, and vomiting, acute fever and headache, consumption of anti-coagulation drugs such as aspirin or warfarin. Intervention: All subjects were randomly selected to receive the placebo (mineral oil, n=11) or supplementation (n=11) with fish oil in capsules (American,Vita Cost) of 6 gr daily, containing 3.6 gr of n-3 PUFA (2400 mg of eicosapentaenoic acid and 1200 mg of docohexaenoic acid per day) for 4 weeks. Blood samples (10 ml) will collected at the 48hr before beginning of the study and at the 48hr after end of supplementation period. Main outcome measures: The levels of different cytokines including TNF-alpha, IL-1, IL-6, IL-10, IFN-gamma, and IL-4 will be investigated in the supernatant of polyclonally stimulated peripheral blood mononuclear cells using enzyme-linked immunosorbent assay (ELISA) kits at the 48hr before beginning of the study and at the 48hr after end of supplementation period. Moreover, we will enumerate the frequencies of Th1 and Th2 cells in the peripheral blood of all subjects by flow cytometry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081618814N1**
Registration date: **2014-12-26, 1393/10/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-26, 1393/10/05

Registrant information

Name
Farhad Jadidi-Niaragh
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Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2014-12-28, 1393/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Omega-3 supplementation on immune responses in elite paddlers

Public title
Effect of Omega-3 supplementation on immune responses in elite paddlers
Purpose
Basic scienece
Inclusion/Exclusion criteria
The main inclusion criteria: 18 to 30 years of age, non-smoking, agree to avoid sea foods throughout the study,sign informed consent. The main exclusion criteria: History of cardiovascular disease or diabetes, allergy to fish oil, appearance of intestinal side effects such as chronic and acute abdominal pains, diarrhea, and vomiting, acute fever and headache, consumption of anti-coagulation drugs such as aspirin or warfarin.
Age
From **18 years** old to **30 years** old
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **22**
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
Ethical Committee of Tehran University of Medical Sciences
Street address
Ethical Committee of Tehran University of Medical Sciences, Keshavarz boulevard, Tehran, PO Box 6446-14155, Iran
City
Tehran
Postal code
Approval date
2014-10-28, 1393/08/06
Ethics committee reference number
93-02-27-25916-128511

Health conditions studied

1

Description of health condition studied
It has not ICD10 code.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
age
Timepoint
prior to study
Method of measurement
Questionnaire

2

Description
Height
Timepoint
prior to study
Method of measurement
meter

3

Description
Weight
Timepoint
prior to study
Method of measurement
balance

4

Description
lean body mass
Timepoint
prior to study
Method of measurement
InBody-520 instrument

5

Description
Blood fat
Timepoint
prior to study
Method of measurement
laboratory

6

Description
maximal oxygen uptake
Timepoint

prior to study
Method of measurement
CASMED instrument

Secondary outcomes

1

Description
TNF-alpha level
Timepoint
48 hr before and after study period
Method of measurement
ELISA

2

Description
IL-1beta
Timepoint
48 hr before and after study period
Method of measurement
ELISA

3

Description
IL-6 level
Timepoint
48 hr before and after study period
Method of measurement
ELISA

4

Description
IFN-gamma level
Timepoint
48 hr before and after study period
Method of measurement
ELISA

5

Description
IL-4 level
Timepoint
48 hr before and after study period
Method of measurement
ELISA

6

Description
IL-10 level
Timepoint
48 hr before and after study period
Method of measurement
ELISA

7

Description
Th1 frequency
Timepoint
48 hr before and after study period
Method of measurement
Flow cytometry

8

Description
Th2 frequency
Timepoint
48 hr before and after study period
Method of measurement
Flow cytometry

Intervention groups

1

Description
Test group: subjects in test group will recievel 6.0 g/day fish-oil supplementation in capsules (American,Vita Cost) containing 3.6 g of n-3 polyunsaturate fatty acids containing 2400 mg of EPA and 1200 mg DHA for 4 weeks. Moreover, They will experience the increasing intensive exercise during the same time.Blood samples will be collected 48hr before and after study period.
Category
Other

2

Description
Placebo group: Subjects in placebo group will receive 6gr/day placebo capsules containing mineral oil purchased from Zahravi Pharmaceutical Inc. (Iran) for 4 weeks. Moreover, all subjects will experience the increasing intensive exercise. Blood samples will be collected 48hr before and after study period.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran sailing federetion
Full name of responsible person
Gholamreza Amini
Street address
Sailing tower, Azadi Sport Complex, Tehran-Karaj Highway, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Masud Yunesian
Street address
Vice chancellor for research, Tehran University of Medical Sciences, Keshavarz boulevard, Tehran, PO Box 6446-14155, Iran
City
Tehran

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, Tehran 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
Name of organization / entity
Tehran University of Medical Sciences
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Position
PhD student of Immunology
Other areas of specialty/work
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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