

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Summary

Objectives: An investigation of the immunomodulatory 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 docosahexaenoic acid per day) for 4 weeks. Blood samples (10 ml) will be 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

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 88953021009821

##### Email address

f-jadidin@razi.tums.ac.ir

##### 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 science

**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 receive 6.0 g/day fish-oil supplementation in capsules (American, Vita Cost) containing 3.6 g of n-3 polyunsaturated 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 federation

**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

**Full name of responsible person**

Farhad Jadidi-Niaragh

**Position**

PhD student of Immunology

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

Department of Immunology, School of Public Health, Tehran University of Medical Sciences, Keshavarz boulevard, Tehran, PO Box 6446-14155, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8895 4913

**Fax****Email**

f-jadidin@razi.tums.ac.ir;

farhad\_jadidi1986@yahoo.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

Farhad Jadidi-Niaragh

**Position**

PhD student of Immunology

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Department of Immunology, School of Public Health, Tehran University of Medical Sciences, Keshavarz boulevard, Tehran, PO Box 6446-14155, Iran

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f-jadidin@razi.tums.ac.ir;

farhad\_jadidi1986@yahoo.com

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

Tehran University of Medical Sciences

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**Fax****Email**

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farhad\_jadidi1986@yahoo.com

**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*