

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effect of $\omega$ 3 fatty acids supplementation on levels of PPAR $\gamma$ and UCP2 genes expression, serum level of UCP2 protein, metabolic status, and appetite in elite male athletes: a randomized control trial

#### Protocol summary

##### Study aim

The aim of the present study was to investigate the effect of 3-fatty acid supplementation on the expression levels of PPAR $\gamma$  and UCP2 genes, serum levels of UCP2 protein, metabolic status and appetite in elite male athletes.

##### Design

A randomized, double-blind, placebo-controlled clinical trial

##### Settings and conduct

The study call will be distributed in Tabriz's clubs and sports centers and volunteer athletes will be enrolled.

##### Participants/Inclusion and exclusion criteria

36 athletes with a body mass index of 20 to 30 kg / m<sup>2</sup> will be included in the study. Criteria for excluding are receiving 3-fatty acid supplement in last month or chronic diseases and blood coagulation diseases.

##### Intervention groups

Supplement group will be given two milligrams of 1,000 mg daily of soft gel supplementation daily. In the placebo group, the soft gel similar to the supplement group, will be given by paraffin content.

##### Main outcome variables

Change in expression of PPAR $\gamma$  gene; UCP2 gene; UCP2 protein serum level; metabolic status; appetite

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190625044008N1**

Registration date: **2019-12-19, 1398/09/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-19, 1398/09/28**

Update count: **0**

##### Registration date

2019-12-19, 1398/09/28

##### Registrant information

###### Name

sara moradi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3720 1222

###### Email address

samoradi678@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-10-02, 1398/07/10

##### Expected recruitment end date

2019-12-31, 1398/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of  $\omega$ 3 fatty acids supplementation on levels of PPAR $\gamma$  and UCP2 genes expression, serum level of UCP2 protein, metabolic status, and appetite in elite male athletes: a randomized control trial

##### Public title

The effect of  $\omega$ 3 fatty acids supplementation in elite male athletes

##### Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

No history of chronic and/or blood coagulation diseases  
Range of BMI of 18.5 to 25 kg / m<sup>2</sup> Willingness to participate in the study Age 20- 30 years

### Exclusion criteria:

Received  $\omega$ 3 fatty acids supplements in last month

## Age

From **20 years** old to **30 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

From among the volunteers to participate in the study, 36 individuals will be selected by simple randomization. Then by using the Random Allocation Software, the subjects will be allocated into either fatty Acid Supplements  $\omega$ 3 or placebo group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, the main researchers (including students, tutors, and advisors) as well as the participants will be unaware of the type of supplement (fatty acid supplement 3 or placebo) received by each group. The person responsible for the packaging of supplements that is completely unrelated to the study will be required to assign a three-digit code to each package and keep the codes until the end of the study and analysis of the data.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Research Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Goltasht St.

##### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166/1573113

#### Approval date

2019-10-30, 1398/08/08

#### Ethics committee reference number

IR.TBZMED.REC.1398.782

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

Anthropometric measures

#### Timepoint

Baseline and 3 weeks after intervention

#### Method of measurement

Measurement of height and weight without shoes and with minimum clothes on, by Seca stadiometer and scale, respectively. Calculation of body mass index (BMI) by dividing weight (Kg) by height squared (m<sup>2</sup>)

### 2

#### Description

Body composition

#### Timepoint

Baseline and 3 weeks after intervention

#### Method of measurement

Bioelectrical Impedance Analysis (BIA) to determine Fat mass (FM), Fat free mass (FFM), and Body water (BW)

### 3

#### Description

Resting metabolic rate

#### Timepoint

Baseline and 3 weeks after intervention

#### Method of measurement

Indirect calorimetry

### 4

#### Description

Blood pressure

#### Timepoint

Baseline and 3 weeks after intervention

#### Method of measurement

Stethoscope

## **5**

### **Description**

Appetite status

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Visual analogue scale

## **6**

### **Description**

Serum UCP2 protein level

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

ELISA

## **7**

### **Description**

Uncoupling protein2 gene expression

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Real-time polymerase chain reaction (PCR)

## **8**

### **Description**

Peroxisome proliferator-activated receptors gamma gene expression

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Real-time polymerase chain reaction (PCR)

## **9**

### **Description**

Serum triglycerides

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Autoanalyzer kit

## **10**

### **Description**

Serum low density lipoprotein cholesterol

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Calculation of LDL-cholesterol by Friedewald equation

## **11**

### **Description**

Serum high density lipoprotein cholesterol

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Autoanalyzer kit

## **12**

### **Description**

Total cholesterol

### **Timepoint**

Baseline and 3 weeks after intervention

### **Method of measurement**

Autoanalyzer kit

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: soft gel supplement fatty acid  $\omega$ 3 daily 2 soft gel, dose of 1 g with lunch and dinner for 3 weeks

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: soft gel placebo (paraffin) daily 2 soft gel, dose of 1 g with lunch and dinner for 3 weeks

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Faculty of Nutrition and Food Sciences

##### **Full name of responsible person**

Sara Moradi

##### **Street address**

Faculty of Nutrition and Food sciences, Tabriz  
University of Medical Sciences Attar Neishabouri St.,  
Tabriz, I. R. Iran

##### **City**

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##### **Province**

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##### **Postal code**

5166614711

##### **Phone**

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##### **Email**

samoradi678@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Ostad Rahimi

**Street address**

Faculty of Nutrition and Food Sciences, Attar  
Neyshabouri Av., Golgasht St.

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sara Moradi

**Position**

Ph.D. Student in Nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Attar-e Nishaboori ST- Faculty of Nutrition and Food  
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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Beit Allah Alipour

**Position**

Professor of Nutrition, in Faculty of Nutrition and Food  
Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Full name of responsible person**

Sara Moradi

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to  
make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available