

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effect of ω 3 fatty acids supplementation on levels of PPAR γ 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 γ 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 / m² 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 γ 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)

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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 ω 3 fatty acids supplementation on levels of PPAR γ 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 ω 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 / m² Willingness to participate in the study Age 20- 30 years

Exclusion criteria:

Received ω 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 ω 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.

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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 (m²)

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 ω 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

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Dr. Beit Allah Alipour

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Professor of Nutrition, in Faculty of Nutrition and Food
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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