Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Dec 2021

The effect of ω3 fatty acids supplementation on levels of PPARγ 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 PPARγ 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 2 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 PPARγ 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
saramoradi678@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 ω3 fatty acids supplementation on levels of PPARγ 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 ω3 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 2 Willingness to participate in the study Age 20– 30 years

Exclusion criteria:

Received ω3 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 ω3 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., Golgasht 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 (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 ω3 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
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 7584
Email
saramoradi678@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.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 7582

Email
nut-rc@tbzmed.ac.ir

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 Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5183874384

Phone
+98 41 3441 5282

Email
saramoradi678@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

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
Nutrition

Street address
Attar-e Nishaboori ST, Faculty of Nutrition and Food Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5183874384

Phone
+98 41 3335 7584

Email
alipourb@tbzmed.ac.ir

Person responsible for updating data

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
Nutrition faculty, Tabriz University of Medical Sciences, Attar neyshabori Ave., Golgash Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5183874384

Phone
+98 83 3720 1222

Fax

Email
saramoradi678@gmail.com

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