

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of comparison the effect of Astashrimp oil supplement and placebo on antioxidant level, inflammatory markers and cardio-metabolic risk factors in 10-18 years old participants with metabolic syndrome

Protocol summary

2017-06-06, 1396/03/16

Summary

This study is a randomized controlled clinical trial of triple-blind, parallel group, which will be carried out for 8 weeks for assessing antioxidant level, inflammatory markers and cardio-metabolic risk factors. Inclusion criteria were the age range of 10-18, no special diet for at least 2 months, no taking of NSAIDs (Ibuprofen, Aspirin, Warfarin, etc.) and thyroid, drugs that reduce appetite and decrease fat and blood sugar, the use of hormone therapy, sedatives, antidepressants and anticoagulants. subjects can leave the study in the absence of consent at any stage of the study. Exclusion criteria included lack of proper use of drugs or placebo, people who are allergic to fish and any seafood and fish oil as well as taking anticoagulants and people with hemophilia. They were randomly assigned to one of two groups receiving the supplement and placebo. A 500 mg soft gel Astashrimp oil for intervention and placebo for the control group will be administered for 8 weeks. One capsule will use a day after breakfast. For those who are enrolled, the demographic questionnaire was completed. To ensure the stability of dietary intakes, a 24-hour dietary recall will be taken at the beginning and at the end of the study. Data on physical activity will be achieved through questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050133747N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Motahar Heidari-Beni

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3320

Email address

motahar.heidari@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison the effect of Astashrimp oil supplement and placebo on antioxidant level, inflammatory markers and cardio-metabolic risk factors in 10-18 years old participants with metabolic syndrome

Public title

The effect of Astashrimp oil supplement on antioxidant level, inflammatory markers and cardio-metabolic risk factors

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the age range of 10-18; no special diet for at least 2 months; no taking of NSAIDs (Ibuprofen, Aspirin, Warfarin, etc.) and thyroid; drugs that reduce appetite and decrease fat and blood sugar; the use of hormone therapy, sedatives, antidepressants and anticoagulants. Exclusion criteria: lack of proper use of drugs or placebo; people who are allergic to fish and any seafood and fish oil; taking anticoagulants; people with hemophilia.

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezarjirib street, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2016-11-15, 1395/08/25

Ethics committee reference number

IR.MUI.REC.1395.2.135

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Total antioxidant capacity

Timepoint

Before and after the intervention

Method of measurement

μmol/L

2

Description

Total cholesterol

Timepoint

Before and after the intervention

Method of measurement

mg/dl

3

Description

Low density lipoprotein-cholesterol

Timepoint

Before and after the intervention

Method of measurement

mg/dl

4

Description

High density lipoprotein-cholesterol

Timepoint

Before and after the intervention

Method of measurement

mg/dl

5

Description

Triglycerides

Timepoint

Before and after the intervention

Method of measurement

mg/dl

6

Description

Blood pressure

Timepoint

Before and after the intervention

Method of measurement

mmhg with sphygmomanometer

7

Description

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

mg/dl

8

Description

Insulin

Timepoint

Before and after the intervention

Method of measurement

μU/ml

9

Description

Interleukin 6

Timepoint

Before and after the intervention

Method of measurement

pg/ml

10

Description

Tumor necrosis factor-alpha

Timepoint

Before and after the intervention

Method of measurement

pg/ml

11

Description

high-sensitivity C-reactive protein

Timepoint

Before and after the intervention

Method of measurement

mg/dl

12

Description

Weight

Timepoint

Before and after the intervention

Method of measurement

Kg with scale

13

Description

Waist circumference

Timepoint

Before and after the intervention

Method of measurement

Cm

Secondary outcomes

1

Description

Waist to hip ratio

Timepoint

before and after intervention

Method of measurement

Calculation

Intervention groups

1

Description

500 mg soft gel Astashrymp oil that is produced by Canadian companies will be consumed for 8 weeks.

Category

Treatment - Drugs

2

Description

One soft gel containing corn oil will be consumed for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Isfahan University of Medical Sciences

Full name of responsible person

Street address

Hezar jrib street, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Prof. Roya Kelishadi

Street address

Hezar jrib street, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Dr Motahar Heidari-Beni

Position

PhD

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

Hezarjrib street, Isfahan University of Medical Sciences, Research Institute for Primordial Prevention of Non-communicable Disease, Isfahan, Iran

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Postal code**Phone**

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Fax**Email**

motahar.heidari@nutr.mui.ac.ir

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

Isfahan University of Medical Sciences

Full name of responsible person

Pro Roya Kelishadi

Position

Pediatrician

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

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

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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