Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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 AstaShrymp 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

2017-06-06, 1396/03/16

Registrant information

Name
Motahar Heidari-Beni
Name of organization / entity
Isfahan university of medical sciences
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Iran (Islamic Republic of)
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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
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Hezarjrib street, Isfahan University of Medical Sciences, Research Institute for Primordial Prevention of Non-communicable Disease, Isfahan, Iran
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Person responsible for scientific inquiries

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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