Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of aerobic training along with spirulina supplementation on markers of hepatic, cardiovascular, lipid profile and anthropometric indices in women with overweight and obesity

Protocol summary

Study aim
Determining of the effects of aerobic training along with spirulina supplementation on markers of hepatic, cardiovascular, lipid profile and anthropometric indices in women with overweight and obesity

Design
Clinical trial with control group, with factorial groups, single-blind, randomized, phase 3 on 40 people. For randomization, block design is used.

Settings and conduct
Referral to a private clinic in Ramsar in 1399, selection of 40 people based on inclusion criteria, randomization into 4 groups, intervention and aerobic training for 8 weeks, completion of the individual consent, physical activity and 24-hour recall questionnaires, receiving 5 Cc of blood before and after the intervention. Blinding of statistical analyzer, coding by a third party who does not know the details.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study Women between 20 to 50 years old Body mass index (BMI) between 25 to 35 (kg / m2), Exclusion criteria: Use of other dietary supplements, probiotics and anti-inflammatory drugs, Use of any antioxidant supplements in the last 3 months, Use of immunosuppressive drugs, Following of special diets, Pregnancy, lactation, Smokers, Menopause, Metabolic and chronic diseases

Intervention groups
Supplement: Three capsules 500 mg/d of spirulina, 2) Placebo: (three capsules 500 mg/d containing starch), 3) Aerobic training (three times/week, 1 hour each time) and three capsules 500 mg/d of spirulina, 4) Aerobic training (three times/week, 1 hour each time) and placebo (three capsules 500 mg/d containing starch)

Main outcome variables
Markers of hepatic, cardiovascular, lipid profile and anthropometric indices

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210103049933N1**
Registration date: **2021-05-19, 1400/02/29**
Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**
Update count: **0**

Registration date
2021-05-19, 1400/02/29

Registrant information

Name
zeinab porasgari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 5525 1015

Email address
porasgarizeynab@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-07-24, 1400/05/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of aerobic training along with spirulina supplementation on markers of hepatic, cardiovascular, lipid profile and anthropometric indices in women with overweight and obesity

Public title
The effects of aerobic training along with spirulina supplementation in women with overweight and obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Women between 20 to 50 years old Body mass index (BMI) between 25 to 35 (kg / m2)
Exclusion criteria:
Use of other dietary supplements, probiotics and anti-inflammatory drugs Use of any antioxidant supplements in the last 3 months Use of immunosuppressive drugs Following of special diets Pregnancy, lactation Smokers Menopause Having a history of diabetes, cancer, liver, kidney, thyroid and gastrointestinal diseases
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Assignment of people in each of the study groups (supplement, placebo, aerobic training and supplement, aerobic training and placebo) will be done by "Random allocation software" using classified randomized blocking method (block size: 4). In addition, in order to reduce selection bias error, allocation concealment will be used. This will be done by assigning unit codes (two codes A and B) to each person's capsules. In this way, 60 people will be randomly allocated to supplement (n = 10), placebo (n = 10), aerobic training and supplement (10), aerobic training and placebo (n = 10) groups. In fact, each person will receive a can containing code A or B, and eventually 20 people will receive cans containing code A and 30 people will receive cans containing code B. Also, 20 people in two groups will receive aerobic training in addition to supplement or placebo.
Blinding (investigator's opinion)
Single blinded
Blinding description
In the present study, the statistical analyst will be blinded to the study groups. Before starting the study, the cans containing the respective capsules will be coded by a person other than the researcher (this person will not aware of the details of the research) to A and B, so that the type of received capsules in each group will be blinded for researcher. Also, placebo and supplement capsules will be similar in terms of color, shape, size and taste. In addition, cans containing the supplement and placebo will be quite similar.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Tehran
Street address
Velayat University Complex, Shahid Sohani St., Army Blvd, Imam Ali highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۱۴۸۹۶۳۵۳۷
Approval date
2021-04-20, 1400/01/31
Ethics committee reference number
IR.SSRC.REC.1400.024

Health conditions studied

1

Description of health condition studied
Overweight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Weight
Timepoint
Before and after the intervention
Method of measurement
Seca scale

2

Description
Body mass index
Timepoint

Before and after the intervention

Method of measurement

Weight divided by the square of height in meters (kg / m2)

3

Description

Waist and hip circumference

Timepoint

Before and after the intervention

Method of measurement

Tape metre (cm)

4

Description

Liver enzymes (alanine aminotransferase, aspartate aminotransferase and gamma glutamyl transferase)

Timepoint

Before and after the intervention

Method of measurement

Colorimetric enzymatic method (Pars Azmun)

5

Description

Lipid profile (HDL-c, LDL-c, TG, total cholesterol and VLDL)

Timepoint

Before and after the intervention

Method of measurement

Colorimetric enzymatic method (Pars Azmun)

6

Description

Serum homocysteine

Timepoint

Before and after the intervention

Method of measurement

ELISA

7

Description

Serum levels of C-reactive protein

Timepoint

Before and after the intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Three capsules 500 mg/d of spirulina after each meal for 8 weeks (Made by the German Rocket company)

Category

Lifestyle

2

Description

Control group: Three capsules 500 mg/d containing starch after each meal for 8 weeks (Made by the Faculty of Pharmacy, Mazandaran University of Medical Sciences)

Category

Placebo

3

Description

Intervention group 2: Aerobic training (three times/week, 1 hour each time) and three capsules 500 mg/d of spirulina after each meal for 8 weeks (Made by the German Rocket company)

Category

Lifestyle

4

Description

Intervention group 3: Aerobic training (three times/week, 1 hour each time) and placebo (three capsules 500 mg/d containing starch) after each meal for 8 weeks (Made by the Faculty of Pharmacy, Mazandaran University of Medical Sciences)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Zeynab Porasgari

Street address

No. 133, Mehregan Medical Building, Motahari St., Ramsar, Iran

City

Ramsar

Province

Mazandaran

Postal code

۴۶۹۱۸۴۶۹۴۰

Phone

+98 21 8807 4874

Email

porasgarizeynab@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ali Kashi
Street address
Velayat University Complex, Army Blvd, Shahid Sohani St., Imam Ali highway, Tehran,
City
Tehran
Province
Tehran
Postal code
۱۱۴۸۹۶۳۵۳۷
Phone
+98 21 8807 4874
Email
porasgarizeynab@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
1
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

2

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ali Kashi
Street address
Tehran, Imam Ali highway, Army Blvd, Shahid Sohani St., Velayat University Complex
City
Tehran
Province
Tehran
Postal code
۱۱۴۸۹۶۳۵۳۷
Phone
+98 21 8807 4874
Email
porasgarizeynab@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
99
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zeynab Porasgari
Position
Master of Science
Latest degree
Master
Other areas of specialty/work
Sports Physiology (Sports Nutrition)
Street address
No.133, Mehregan Medical Building, Motahari St, Ramsar, Iran
City
Ramsar
Province
Mazandaran
Postal code
۴۶۹۱۸۴۶۹۴۰
Phone
+98 911 196 0775
Email
porasgarizeynab@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zeynab Porasgari
Position
Master of Scienes
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No.133, Mehregan Medical Building, Motahari St, Ramsar, Iran
City
Ramsar
Province
Mazandaran
Postal code
۴۶۹۱۸۴۶۹۴۰

Phone
+98 911 196 0775
Email
porasgarizeynab@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zeynab Porasgari
Position
Master of Scienes
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No. 133, Mehregan Medical Building, Motahari St, Ramsar, Iran
City
Ramsar
Province
Mazandaran
Postal code
۴۶۹۱۸۴۶۹۴۰
Phone
+98 911 196 0775
Email
porasgarizeynab@yahoo.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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable