Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Determining the effect of 8 weeks of resistance training and spirulina supplementation on levels of asprosin, Glucose, lipid profile and some body composition indices in overweight men

Protocol summary

Study aim

Determining the effect of 8 weeks of resistance training with spirulina on aspirin, glucose, lipid profile and body composition indices of overweight men

Design

Clinical trial with intervention and control groups, Single blind, randomised, Over 60 overweight man, G-Power software medicine is used for randomization.

Settings and conduct

Overweight men who refer to the gyms of Zahedan University of Medical Sciences will be included in the study if they have inclusion criteria, and randomly will be assigned into two groups of intervention and two groups of control applying the permuted block method. This study will be single blind so that participants will not be aware of the contents of the capsules since they may think the capsules contain spirulina.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 50-30 years old, General physical and mental health, Body mass index more than 25 kg/m2. Exclusion criteria: having exercised regularly during 6 months before the start of training sessions, suffering from cardiovascular diseases, diabetes, hormonal disorders, kidney, or liver diseases, Being a smoker, having recently had any surgery or medical interventions

Intervention groups

Intervention group 1: Exercise with spirulina, two spirulina capsules 500 mg daily (Made by Reyhaneh Pharmaceutical Company of Isfahan) for 8 weeks and resistance training 3 sessions per week for 8 weeks. Intervention group 2: Spirulina, two capsules of Spirulina 500 mg daily (Made by Reyhaneh Pharmaceutical Company of Isfahan) for 8 weeks. Control group 1: Placebo exercise, two placebo capsules 500 mg daily (Made by Reyhaneh Pharmaceutical Company of Isfahan) for 8 weeks and resistance training 3 sessions per week for 8 weeks. Control group 2: placebo, two placebo capsules 500 mg daily (Made by Reyhaneh Pharmaceutical Company of Isfahan) for 8 weeks.

Main outcome variables

levels of asprosin, Glucose, lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029322N4**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **retrospective**

Last update: **2021-11-09, 1400/08/18**
Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name
Hossein Nakhei
Name of organization / entity
University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of 8 weeks of resistance training and spirulina supplementation on levels of asprosin, Glucose, lipid profile and some body composition indices in overweight men

Public title

The effect of exercise and spirulina supplementation on the Asprosin hormone in overweight men

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 50-30 years old General physical and mental health Body mass index (BMI) more than 25 kg / m 2

Exclusion criteria:

If the participant has exercised regularly during 6 months before the start of training sessions If the participant has suffers from cardiovascular diseases If the participant has suffers from diabetes disease If the participant has suffers from hormonal disorders disease If the participant has suffers from kidney disease If the participant has suffers from liver disease If the participant is a smoker If the participant has recently had any surgery or medical interventions

Age

From **30 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Out of all the population, a number of 60 overweight men will be selected using G-Power software. Individuals will be divided into four groups by the permuted block method with blocks size 4 as A: placebo, B: spirulina with training, C: training with placebo, and D: spirulina

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a single blind, clinical trial study. It is single blind in spirulina and placebo groups. The subjects will study the research protocol in the first session. The supplement and placebo will be in the same capsules. The capsules will be distributed among the participants. Only the researcher knows the contents of the capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

university/regional research Ethics committee Zahedan University of medical sciences

Street address

Medical Sciences Campus- Dr. Hesabi Square- Zahedan City- Sistan and Baluchestan Province

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.ZAUMS.REC.1400.056

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

Asprosin

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Plasma Asprosin levels were measured using an ELISA kit (Zell Bio Co made in Germany with a sensitivity of 0.05 ng/m), and ELISA-by-ELISA Reader (US lotion model).

2

Description

Glucose

Timepoint
Before the intervention and two months after the intervention
Method of measurement
ParsAzmon Kit (mg/dl)

3

Description
triglyceride
Timepoint
Before the intervention and two months after the intervention
Method of measurement
ParsAzmon Kit (mg/dl)

4

Description
Cholesterol
Timepoint
Before the intervention and two months after the intervention
Method of measurement
ParsAzmon Kit (mg/dl)

5

Description
High Density Lipoprotein
Timepoint
Before the intervention and two months after the intervention
Method of measurement
ParsAzmon Kit (mg/dl)

6

Description
Low Density Lipoprotein
Timepoint
Before the intervention and two months after the intervention
Method of measurement
ParsAzmon Kit (mg/dl)

Secondary outcomes

1

Description
Least body mass
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Body composition analyzer, model IOI 353, made by Jawon Medical, South Korea.

2

Description
Lean body mass
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Body composition analyzer, model IOI 353, made by Jawon Medical, South Korea.

3

Description
Waist to height ratio
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Height will be measured with Sahand Company's height meter and Waist circumference will be measured with a Tape meter (made in Iran).

Intervention groups

1

Description
Intervention group 1: Training with spirulina: Spirulina group will take two 500 mg spirulina capsules daily (morning and evening) for eight weeks. Rayhaneh Pharmaceutical Company of Isfahan will provide Spirulina supplement. Resistance training will be implemented for eight weeks, 3 sessions each week, and in 12 movements with 1, 2, 3, and 4-minute rest intervals, and 40, 60, 75, and 90 percent of a maximum repetition, using a flexible scheduling pattern, and an additional principle. Exercises will be performed in a gym in Zahedan.
Category
Rehabilitation

2

Description
Intervention group 2: spirulina. Spirulina group will take two 500 mg spirulina capsules daily (morning and evening) for eight weeks. Rayhaneh Pharmaceutical Company of Isfahan will provide Spirulina supplement.
Category
Treatment - Drugs

3

Description
Control group 1: Training With placebo. The placebo group will take two 500 mg capsules of starch daily for eight weeks. The placebo will be provided by Reyhaneh Pharmaceutical Company of Isfahan. Resistance training will be implemented for eight weeks, 3 sessions each week, and in 12 movements with 1, 2, 3, and 4-minute rest intervals, and 40, 60, 75, and 90 percent of a maximum repetition, using a flexible scheduling pattern, and an additional principle. Exercises will be performed in a gym in Zahedan.
Category
Rehabilitation

4

Description
Control group 2: Placebo. The placebo group will take two 500 mg capsules of starch daily for eight weeks. The placebo will be provided by Reyhaneh Pharmaceutical Company of Isfahan.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat Sports Hall, Zahedan University of Medical Sciences

Full name of responsible person
Hossein Nakhaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
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Web page address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Hossein Nakhaei

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data including: (IPD), study protocol, statistical analysis map, informed consent form, clinical study report and data dictionary will be published upon completion of the study. Participants' identities will not be released.
When the data will become available and for how long
Data will be available immediately upon completion of the project. It will probably be released in 1401.
To whom data/document is available
For researchers of academic and scientific institutions
Under which criteria data/document could be used
For the development of related sciences
From where data/document is obtainable
Refer to Zahedan University of Medical Sciences by letter
What processes are involved for a request to access data/document
Submit a valid letter from the scientific centres
Comments