

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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/m<sup>2</sup>. 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)

##### Phone

+98 54 3341 1374

##### Email address

h.nakhaei@zaums.ac.ir

##### 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<sup>2</sup>  
**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

###### **Street address**

Velayat Sports Hall- Main campus- Dr. Hesabi Square

###### **City**

Zahedan

###### **Province**

Sistan-va-Balouchestan

###### **Postal code**

9816743463

###### **Phone**

+98 54 3329 5765

###### **Email**

dsc@zaums.ac.ir

###### **Web page address**

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Zahedan University of Medical Sciences

###### **Full name of responsible person**

Dr Nour Mohammad Bakhshani

###### **Street address**

Vice chancellor of researches and technology- Main campus- Dr. Hessabi Square

###### **City**

Zahedan

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Sistan-va-Balouchestan

###### **Postal code**

9816743463

###### **Phone**

+98 54 3337 2117

###### **Fax**

+98 54 3337 2117

###### **Email**

zaums.research@gmail.com

###### **Web page address**

<http://research.zaums.ac.ir/>

###### **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

###### **Street address**

Main campus, Dr. Hassabi Square

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[hossiennakhaie@yahoo.com](mailto:hossiennakhaie@yahoo.com)

#### **Person responsible for scientific 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.

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hossein Nakhaei

**Position**

Assistant Professor

**Latest degree**

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**