

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of 6 weeks of spinning and stationary bicycle trainings on serum levels of Asprosin and PBF in overweight and obese women.

#### Protocol summary

##### Study aim

Effect of 6 weeks of spinning and stationary bicycle training on serum levels of Asprosin and PBF in overweight and obese women.

##### Design

Clinical trial with control group (n = 15), with parallel groups [spinning exercise group (n = 15), Bike training group (n = 15)], Single blind, randomised trial

##### Settings and conduct

This is a clinical trial. This study will be a single blind study. The population of the study is obese and overweight women in the city. 60 members of the sports clubs are selected. They were randomly assigned to the (20 spinning training), (20 bicycle training), and (20 control group) groups.

##### Participants/Inclusion and exclusion criteria

Participants included obese and overweight women. The study involved 45 eligible people. They will be randomly assigned to the spinning exercise group (n = 15), the bike training group (n = 15) and the control group (n = 15). Inclusion criteria: General physical and mental health, Body mass index (BMI) More than 25 kg / m<sup>2</sup>, Not having regular exercise for 6 months before starting training Participation in exercise activities, disease during exercise, pregnancy during exercise, and non-participation in each of the test groups Exclusion criteria: Participate in regular sports activities, Disease during exercise, Pregnancy during exercise, Refusing to continue cooperation

##### Intervention groups

spinning exercise group (n = 15), Bike training group (n = 15) and the control group (n = 15).

##### Main outcome variables

Asprosin, Fat percentage (kg/m<sup>2</sup>)

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160813029322N2**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

#### Registration date

2020-04-17, 1399/01/29

#### 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

2020-02-20, 1398/12/01

#### Expected recruitment end date

2020-04-18, 1399/01/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of 6 weeks of spinning and stationary bicycle trainings on serum levels of Asprosin and PBF in overweight and obese women.

## Public title

The effect of exercise on the Asprosin hormone in overweight and obese women

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age: 25-40 years General physical and mental health  
Body mass index (BMI) more than 25 kg / m<sup>2</sup> Not having regular exercise for 6 months before starting training Not having diseases: cardiovascular, diabetes, hormonal disorders, kidney and liver diseases, surgery, tobacco use and any medical intervention

### Exclusion criteria:

Participate in regular sports activities Disease during exercise Pregnancy during exercise Refusing to continue cooperation

## Age

From **25 years** old to **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted block

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Blood samples are collected. It is coded on the samples. Samples are taken to the laboratory for hormone measurement.

## Placebo

Not 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

Main campus, Zahedan, Sistan and Baluchestan, Iran

##### City

Zahedan

## Province

Sistan-va-Balouchestan

## Postal code

9816743463

## Approval date

2020-02-02, 1398/11/13

## Ethics committee reference number

IR.ZAUMS.REC.1398.445

## Health conditions studied

### 1

#### Description of health condition studied

Obesity and overweight

#### ICD-10 code

E66

#### ICD-10 code description

Overweight and obesity

## Primary outcomes

### 1

#### Description

Heart rate

#### Timepoint

Six weeks, One sessions a week

#### Method of measurement

Heartbeat watch

### 2

#### Description

Maximum oxygen consumption

#### Timepoint

Six weeks, One sessions a week

#### Method of measurement

Treadmill

## Secondary outcomes

### 1

#### Description

Asprosin

#### Timepoint

Before the intervention and two months after the intervention

#### Method of measurement

Asprosin Kit (ELISA ng/ml)

### 2

#### Description

Fat percentage (kg/m<sup>2</sup>)

#### Timepoint

Before the intervention and two months after the intervention

#### Method of measurement

Related formula  $BF\% = (0.41563 * X) - (0.00112 * 2) X + (0.03663 * Y) + 4.03653$

## Intervention groups

### 1

#### Description

Intervention group: Spinning bicycle training, Training will be done by Spinning bicycle, It will take six weeks (three day a week, one hour each session).

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Stationary bicycle training, Training will be done by Stationary bicycle, It will take six weeks (three day a week, one hour each session).

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zahedan University of Medical Sciences

##### Full name of responsible person

Hossein Nakhaei

##### Street address

Main campus, Dr. Hesabi Square

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5765

##### Email

hossiennakhaie@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Dr Seyed Mohammad Hashemi Shahri

##### Street address

Main campus, Dr. Hessabi Square

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5715

##### Email

hossiennakhaie@yahoo.com

##### Web page address

http://zaums.ac.ir/default.page

##### 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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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Hossein Nakhaei

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

**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. This data will be published in a valid journal article format.

**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 1400.

**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****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.

**Other areas of specialty/work**

Physiology

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