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 / m², 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 2)

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.
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/m² 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

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

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/m²)

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 5765
Email
hossiennakhaie@yahoo.com

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
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5765
Email
hossiennakhaie@yahoo.com

Person responsible for general inquiries

Person responsible for scientific inquiries
Street address
Main campus, Dr. Hessabi Square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5765

Email
hossiennakhaie@yahoo.com

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

Street address
Main campus, Dr. Hessabi Square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5765

Email
hossiennakhaie@yahoo.com

Web page address
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