

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the metabolic factors in obese patients' pre and post bariatric surgery after 3 months trial of aerobic versus strengthening exercises

Protocol summary

Summary

Study Goal: is comparing the effectiveness of home-based aerobic exercise training versus supervised aerobic or strength exercise training on metabolic factors in post bariatric surgery patients. Study population and methods: study population will include 90 obese patients who are eligible for bariatric surgery. We'll measure each patients' Fasting Blood sugar, High density Lipoprotein, Low Density Lipoprotein, Triglyceride ,HOMAIR, Hemoglobin A1C , physical fitness using 6 minute walk test, as well as muscle strength using dynamometer, before their surgery, 6 weeks post- op, and 3 months after patients participation in either aerobic or strengthening exercise programs. Patients will get randomized to 3 different groups as follow: Group 1: includes 30 patients who will receive conventional therapy, which includes one hour session of training on how to do aerobic exercise, supplemental handbook as a reminder for exercises they are supposed to do as well as a pedometer to keep track of their physical activity . Group 2: includes 30 patients who will receive conventional therapy plus 2 sessions of strength training per week each for an hour under supervision of a Sports Medicine physician Group 3: Includes 30 patients who'll receive 2 hourly sessions of aerobic exercise per week supervised by a sport medicine specialist in addition to conventional therapy. At the end of the 3 months we'll re-measure all the metabolic parameters and compare them to the initial values to find out if our intervention by using supervised training make a difference between the values of 3 different groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111214251N8**

Registration date: **2011-12-05, 1390/09/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-05, 1390/09/14

Registrant information

Name

Haleh Dadgostar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 4050

Email address

dadgostar.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2012-08-05, 1391/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the metabolic factors in obese patients' pre and post bariatric surgery after 3 months trial of

aerobic versus strengthening exercises

Public title

Comparison of the metabolic factors in obese patients' pre and post bariatric surgery after 3 months trial of aerobic versus strengthening exercises

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: bariatric surgery in the 1-3 months ago. Exclusion criteria: 1. Those with heart disease including heart valve disease , ischemic heart disease, uncontrolled symptomatic arrhythmias, cardiovascular hypertrophic myopathy; 2. Patients with high systolic blood pressure ≥ 200 and high diastolic blood pressure ≥ 90 ; 3. Uncontrolled metabolic diseases; 4. neuromuscular, Musculoskeletal and rheumatoid disease that resonance with exercise; 5. Acute pulmonary embolism; 6. Symptomatic chronic heart failure.

Age

From **15 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of medical sciences

Street address

Ghods street, Keshavarz Boulevard

City

Tehran

Postal code

1417653761

Approval date

2011-11-19, 1390/08/28

Ethics committee reference number

1762, 130, 90 ,ص

Health conditions studied

1

Description of health condition studied

Morbid obesity

ICD-10 code

E66.8

ICD-10 code description

Morbid obesity

Primary outcomes

1

Description

Fasting Blood sugar

Timepoint

befor surgery-6week after surgery-4.5 month after surgery

Method of measurement

kit in labaratory

2

Description

High density Lipoprotein

Timepoint

befor surgery-6week after surgery-4.5 month after surgery

Method of measurement

kit in labaratory

3

Description

Low Density Lipoprotein

Timepoint

befor surgery-6week after surgery-4.5 month after surgery

Method of measurement

kit in labaratory

4

Description

Triglyceride

Timepoint

befor surgery-6week after surgery-4.5 month after surgery

Method of measurement

kit in labaratory

5

Description

HOMAIR

Timepoint

befor surgery-6week after surgery-4.5 month after surgery

Method of measurement

kit in labaratory

6

Description

Hemoglobin A1C

Timepoint

before surgery, 4-6 weeks after surgery and 4.5 month after surgery and exercise therapy

Method of measurement

kit in laboratory

Secondary outcomes

1

Description

heart rate

Timepoint

before surgery-6week after surgery-4.5 month after surgery

Method of measurement

stethoscope

2

Description

waist circumference

Timepoint

before surgery-6week after surgery-4.5 month after surgery

Method of measurement

in centimeters by Tape

3

Description

Weight

Timepoint

before surgery-6week after surgery-4.5 month after surgery

Method of measurement

in kilograms by Balance

Intervention groups

1

Description

First group: this group will be training aerobic and strength exercise and hand book will be given to all patients for how to do these exercises as well as Pedometer that given for register the amount of physical activity during the week . (conventional therapy)

Category

Lifestyle

2

Description

Group B: In addition to conventional therapy, strength training,two sessions per week for one hour will be doing under the supervision of a sport medicine specialist.

Category

Lifestyle

3

Description

Group III: In addition to conventional therapy, patients of this group will be doing aerobic exercise two one-hour sessions per week under the supervision of a sport medicine specialist.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity clinic of Rasoul Akram Hospital

Full name of responsible person

Sara Kaviani, MD

Street address

Rasoul Akram Hospital, Niaesh Street, Sattar Khan Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of medical sciences

Full name of responsible person

Dr Akbar Fotoohi

Street address

Ghods street, Keshavarz boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Haleh Dadgostar, MD

Position

Assistant professor

Other areas of specialty/work**Street address**

Rasoole Akram Hospital, Shar_Ara st., Sattarkhan st

City

Tehran

Postal code**Phone**

+98 21 64351

Fax**Email**

hdadgostar@tums.ac.ir , hldadgostar@gmail.com

Web page address**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran university of medical science

Full name of responsible person

Dr Sara Kaviany

Position

Assistant

Other areas of specialty/work**Street address**

Rasoul Akram Hospital, Niaiesh Street, Sattar Khan Ave.

City

Tehran

Postal code**Phone**

+98 26 1447 0350

Fax**Email**

drsa_kaviani@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Haleh Dadgostar, MD

Position

Assistant professor

Other areas of specialty/work**Street address**

Rasoole Akram Hospital, Shar_Ara st., Sattarkhan st

City

Tehran

Postal code**Phone**

+98 21 64351

Fax**Email**

hdadgostar@tums.ac.ir , hldadgostar@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty