

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

comparison the effects of Sleeve Gastrectomy, Bypass gastrectomy, and SASI bypass on the changes of adiponectin level in obese patients

Protocol summary

Registration timing: **retrospective**

Study aim

evaluation of the adiponectin levels and leptin levels in obese patients 6 months after sleeve gastrectomy, bypass surgery, and SASI bypass surgery

Last update: **2021-01-19, 1399/10/30**

Update count: **0**

Registration date

2021-01-19, 1399/10/30

Design

This is a non-randomized clinical trial with parallel groups. Patients are divided into three groups of 15 selected patients. Adiponectin and leptin levels are measured between patients who underwent three different obesity surgeries in Shiraz. There is no separate control group and each group undergoing surgery is compared to its preoperative one.

Registrant information

Name

Hajar Khazraei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1453

Email address

khazraee@sums.ac.ir

Settings and conduct

The place of work is Shahid Faghihi Hospital and the mother and child of Shiraz. The patient's plasma sample is collected before and after sleeve gastrectomy or bypass or SASI bypass surgery and leptin and adiponectin levels are measured by an ELISA kit. There is no blinding. The results are compared between groups.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

obese patients who underwent bariatric surgery Age 18-90 years old Body Mass Index>25

Expected recruitment start date

2019-05-02, 1398/02/12

Expected recruitment end date

2020-12-02, 1399/09/12

Actual recruitment start date

2019-05-02, 1398/02/12

Actual recruitment end date

2020-12-02, 1399/09/12

Trial completion date

2020-12-02, 1399/09/12

Intervention groups

obese patients who underwent sleeve gastrectomy or two bypass surgeries. Adiponectin and leptin levels were assessed before and 6 months after surgery. All three groups of patients (15 people in each group) are compared to see which changes were greater.

Main outcome variables

Adiponectin levels and inflammatory factors in the patient's serum

Scientific title

comparison the effects of Sleeve Gastrectomy, Bypass gastrectomy, and SASI bypass on the changes of adiponectin level in obese patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201012049000N2**

Registration date: **2021-01-19, 1399/10/30**

Public title

comparison the effects of bariatric surgeries on the changes of adiponectin level in obese patients

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-90 years old obese with BMI>25

Exclusion criteria:

past surgery history in abdominal area endocrinological disorders

AgeFrom **18 years** old to **90 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **15**

45 patients were selected from obese patients who underwent bariatric surgery

Actual sample size reached: **45**

More than 1 sample in each individual

Actual sample size in each individual: **15**

45 patients were selected from obese patients who underwent bariatric surgery

Randomization (investigator's opinion)

Not 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**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Floor 9, Research tower, Khalili street, Shiraz

City

Shiraz

Province

Fars

Postal code

7193635899

Approval date

2018-02-20, 1396/12/01

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Patient serum adiponectin levels

Timepoint

Before and 6 months after surgery

Method of measurement

Kit Elisa

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: obese patients under Sleeve gastrectomy surgery

Category

Treatment - Surgery

2**Description**

Intervention group: obese patients under SASI surgery

Category

Treatment - Surgery

3**Description**

Intervention group: obese patients under Bypass surgery

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mother and Child Hospital

Full name of responsible person

Abbas Rezaeianzadeh

Street address

Colorectal Research Center, Khalili St., Mohammad Rasoolullah Research Tower

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

+98 71 3628 1453

Email

colorectal2@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeianzadeh

Street address

Colorectal research center, Research tower, Khalili street

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

+98 71 3628 1453

Email

colorectal2@sums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

research proposal

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

Shiraz University of Medical Sciences

Full name of responsible person

Hajar Khazraei

Position

Assistant prof.

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Colorectal research center

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

009836281453

Email

khazraee@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hajar Khazraei

Position

Assistant prof.

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

colorectal research center

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

009836281453

Email

khazraee@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hajar Khazraei

Position

Assistant Prof.

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

colorectal research center

City

Shiraz

Province

Fars

Postal code

7193635899

Phone

009836281453

Email

hajarkhazraei@gmail.com

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available