

# 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&gt;25

**Exclusion criteria:**

past surgery history in abdominal area endocrinological disorders

**Age**From **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

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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

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**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

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## Person responsible for scientific inquiries

**Contact**

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Assistant prof.

**Latest degree**

Ph.D.

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**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