

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Investigation the effect of intermittent fasting diet in comparison with calorie restriction diet on pre-, intra- and postoperative clinical outcomes in patients undergoing sleeve gastrectomy surgery: A clinical trial

#### Protocol summary

##### Study aim

Main objective: Determining the effect of intermittent fasting diet compared to calorie restriction diet on clinical outcomes before, during and after operation in patients undergoing sleeve gastrectomy surgery. Secondary objectives: 1-Determination and comparison of anthropometric indicators, liver size, lipid profile, liver enzyme levels at the beginning of the study and before surgery in each group and between the intervention and control groups. 2- Determining and comparing the duration of anesthesia, the duration of surgery, the amount of bleeding during the operation in each group and between the intervention and control groups. 3- Determining and comparing the rate of transfer to the intensive care unit, the duration of hospitalization and the quality of recovery in each group and between the intervention and control groups.

##### Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, on 60 patients, with an easy sampling method, and a table of numbers will be used for randomization.

##### Settings and conduct

Sinai hospital surgery clinic

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age 18-65 years; 2- Body mass index  $\geq 40$ ; Criteria for not entering the study: 1- Vegetarian people; 2- Previous history of bariatric surgery; 3- Diabetic people treated with insulin; 4- People with uncontrolled high blood pressure;

##### Intervention groups

The intervention group of the 16:8 intermittent fasting diet and the control group will follow the calorie restriction diet for one month before the operation.

##### Main outcome variables

Anthropometric indices; liver size; lipid profile; The level of liver enzymes; duration of anesthesia; duration of

surgery; the amount of bleeding during the operation; the rate of transfer to the intensive care unit; duration of hospitalization; Recovery quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200301046655N2**

Registration date: **2023-08-13, 1402/05/22**

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

Last update: **2023-08-13, 1402/05/22**

Update count: **0**

##### Registration date

2023-08-13, 1402/05/22

##### Registrant information

##### Name

Razieh Khalooeifard

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 5975

##### Email address

shkhalooei1367@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation the effect of intermittent fasting diet in comparison with calorie restriction diet on pre-, intra- and postoperative clinical outcomes in patients undergoing sleeve gastrectomy surgery: A clinical trial

**Public title**

Effect of fasting diet in sleeve surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate in the study Body mass index  $\geq 40$  A candidate for elective sleeve gastrectomy surgery American Society of Anesthesiology classification grade: 1-2

**Exclusion criteria:**

Vegetarians Previous history of bariatric surgery Diabetics treated with insulin People with uncontrolled high blood pressure

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this trial, the balanced random block method will be used, with a block size of 4 (combination of A and B as groups). Using the Randomization.com website, random allocation will be done for 60 people in the form of 15 blocks of 4. Since body mass index is an important variable in the intervention effect. This intervention will be implemented in a classified manner. In order to properly implement this trial, a random allocation list will be generated separately for each of the two classes of body mass index 40 to 45 and 45 to 50.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

the principal investigator, the surgeon, the anesthetist, the ward nurses, the person in charge of data collection and the person who evaluates the outcome will not know whether the type of diet received was intermittent fasting or calorie restriction.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics committee of Sina Hospital

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1467664961

**Approval date**

2022-09-28, 1401/07/06

**Ethics committee reference number**

IR.TUMS.SINAHOSPITAL.REC.1401.066

**Health conditions studied****1****Description of health condition studied**

Sleeve gastrectomy surgery

**ICD-10 code**

Z98.84

**ICD-10 code description**

Bariatric surgery status

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

liver size

**Timepoint**

At the beginning of the study (before the start of the intervention) and before surgery

**Method of measurement**

sonography

**2****Description**

Weight

**Timepoint**

At the beginning of the study (before the start of the intervention) and before surgery

**Method of measurement**

scales

### 3

#### **Description**

Body mass index

#### **Timepoint**

At the beginning of the study (before the start of the intervention) and before surgery

#### **Method of measurement**

The ratio of weight (in kilograms) to the second power of height in meters

### 4

#### **Description**

Lipid profile

#### **Timepoint**

At the beginning of the study (before the start of the intervention) and before surgery

#### **Method of measurement**

blood test

### 5

#### **Description**

Liver enzymes

#### **Timepoint**

At the beginning of the study (before the start of the intervention) and before surgery

#### **Method of measurement**

blood test

### 6

#### **Description**

Duration of anesthesia

#### **Timepoint**

From the time of the induction of anesthesia to extubation of the patient

#### **Method of measurement**

in minutes and from the patient's medical record

### 7

#### **Description**

Duration of surgery

#### **Timepoint**

The duration of surgery from the time of prep and drape to the completion of suturing

#### **Method of measurement**

in minutes and from the patient's medical record

### 8

#### **Description**

Duration of hospitalization

#### **Timepoint**

From the time of admission to the surgical department until discharge

#### **Method of measurement**

by day and through the patient's medical record

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Intermittent fasting diet of 16:8 type (16 hours only allowed to receive water, non-energy drinks, tea, coffee and free consumption of food for 8 hours), in case of weakness or headache, it is explained to the participants that they should eat a snack consisting of 200 kilocalories of mixed nuts (18 grams of fat, 5 grams of protein, 4 grams of carbohydrates), in fact a low carbohydrate snack. This diet will be followed for 4 weeks before sleeve gastrectomy surgery.

#### **Category**

Prevention

### 2

#### **Description**

Control group: The calorie restriction diet (after calculating the amount of calories required by the Mifflin method, in which the actual weight is in kilograms and height in centimeters based on the year, and by applying the coefficient of physical activity and calorific value of food, 25% of the total estimated calories will be reduced and the food plan will be adjusted for each person) will be observed for 4 weeks before the sleeve gastrectomy surgery.

#### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sina hospital

##### **Full name of responsible person**

Razieh Khalooeifard

##### **Street address**

Imam Khomeini St, Hassan Abad Square

##### **City**

Tehran

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Fax**

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##### **Email**

hosp\_sina@sina.tums.ac.ir

##### **Web page address**

<https://sinahospital.tums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

**Street address**

Keshavarz Blvd., Qods Corner, Tehran University of Medical Sciences Headquarters

**City**

Tehran

**Province**

Tehran

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**Email**

vcr@sina.tums.ac.ir

**Web page address**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Razieh Khalooeifard

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Sina Hospital, Hassan Abad Square, Imam Khomeini St.

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Razieh Khalooeifard

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

**Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Razieh Khalooeifard

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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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**

There is no further 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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable