

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation and comparison of short-term effects of surgery in patients receiving intensive care and patients receiving care with conventional methods in mini omega bariatric surgery

#### Protocol summary

##### Study aim

Evaluation and comparison of short-term effects of surgery in patients receiving intensive care and patients receiving care with conventional methods in mini omega bariatric surgery

##### Design

Clinical trial with control group with parallel groups, phase 2 on 110 patients

##### Settings and conduct

This study is performed in Al-Zahra Hospital in Isfahan. Patients will be cared for in two ways, comparing the complications of surgery and nausea with vomiting and the length of hospital stay.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years, candidate for mini omega bariatric surgery, patients' consent to enter the study Exclusion criteria: location of the patient away from the hospital, lack of patient cooperation

##### Intervention groups

Intervention group 1: Patients in this group will be treated with intensive care protocol. If a nurse is assigned to each patient, the patient will fast on the day of admission, will receive 1 gram of oral paracetamol before admission, will receive 2 grams of cefazolin or 600 mg of clindamycin, and will be treated with dexamethasone and ondansetron. And no drans will be used for him. Complications of the operation, duration of hospitalization, and nausea and vomiting in the patient will be measured and evaluated. Intervention group 2: Patients in this group will be treated according to the standard care protocol in the hospital. Complications of the operation, duration of hospitalization, and nausea and vomiting in the patient will be measured and evaluated.

##### Main outcome variables

Complications of surgery and vomiting and duration of hospitalization

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210614051574N6**

Registration date: **2021-12-21, 1400/09/30**

Registration timing: **prospective**

Last update: **2021-12-21, 1400/09/30**

Update count: **0**

##### Registration date

2021-12-21, 1400/09/30

##### Registrant information

##### Name

Ghasem Mohammadsharifi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3729 4005

##### Email address

mohammadsharifi.ghasem@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-04, 1400/10/14

##### Expected recruitment end date

2022-02-03, 1400/11/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation and comparison of short-term effects of surgery in patients receiving intensive care and patients receiving care with conventional methods in mini omega bariatric surgery

## Public title

Intensive care in mini omega bariatric surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 18 years Candidate for mini omega bariatric surgery Patient consent to enter the study

### Exclusion criteria:

Location of the patient away from the hospital Patient non-cooperation

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **55**

## 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 Esfahan University of Medical Sciences

##### Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-09-28, 1400/07/06

## Ethics committee reference number

IR.MUI.MED.REC.1400.530

## 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

Complications of the operation

#### Timepoint

The day after discharge and 1 month after surgery

#### Method of measurement

Asking patients and reviewing records

### 2

#### Description

Duration of hospitalization

#### Timepoint

The day after discharge

#### Method of measurement

File review

### 3

#### Description

nausea and vomiting

#### Timepoint

The day after discharge and 1 month after surgery

#### Method of measurement

Asking patients and reviewing records

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

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**Category**

Treatment - Other

**2****Description**

Intervention group 2: Patients in this group will be treated according to the standard care protocol in the hospital. Complications of the operation, duration of hospitalization, and nausea and vomiting in the patient will be measured and evaluated.

**Category**

Treatment - Other

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

Al-Zahra hospital

**Full name of responsible person**

Mohsen Mahmoodieh

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

parsa.alinezhad85@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

**City**

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**Province**

Isfahan

**Postal code**

8174673118

**Phone**

+98 31 3668 0048

**Email**

haghjoo.sh@med.mui.ac.ir

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohsen Mahmoodieh

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

### Contact

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## 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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data can be shared after people have requested.

### When the data will become available and for how long

Six months after publishing the results.

### To whom data/document is available

Academic researchers

### Under which criteria data/document could be used

Scientific uses

### From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

### What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

### Comments