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
Isfehan
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
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.

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
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Isfehan
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
Isfahan
Province
Isfehan
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
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
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Person responsible for scientific inquiries

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Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohsen Mahmoodieh

Position

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Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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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