

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the effect of labetalol and remifentanil on pain control after bariatric surgery

Protocol summary

Study aim

The main purpose of this study was to control the pain of patients undergoing bariatric surgery during and after surgery by using less narcotics and thus preventing further complications.

Design

In this study, 50 patients aged 18-80 years who undergo bariatric surgery with inclusion criteria and not having exclusion criteria will be included. Patients will be randomly divided into two groups receiving labetalol or remifentanil, and each participant will be assigned a code.

Settings and conduct

After sample selection, an equal number of patients are randomly assigned to the two groups of remifentanil and labetalol. Postoperative pain at the time of entry into recovery, 2, 4, 6 and 12 hours after surgery will be recorded for each patient using the VRS.

Participants/Inclusion and exclusion criteria

entry: 1. Conscious satisfaction in patients 2. No contraindications and allergies to remifentanil or labetalol 3. age between 18-80 years 4. Patients with physical condition (ASA) I - III Adults of both sexes 5. Definitive confirmation of non-pregnancy in female patients of reproductive age 6. Patients with addiction 7. Patients with a history of psychological illness 8. Patients with a history of taking beta-blockers or calcium channel blockers
No entry: 1. Patients with cardiac arrhythmias 2. Pregnant or lactating women 3. People with a history of alcohol or drug use in the past 3 months 4. Any other conditions or use of any medication that may interfere with the study

Intervention groups

In the labetalol group, 5 mg / ml of labetalol and in the remifentanil group, 1 µg / kg will be injected before the surgical incision. These doses will then be repeated for patients in each group to maintain hemodynamic stability during the operation (if the MAP is increased by more than 15% compared to baseline or HR > 80 times

per minute).

Main outcome variables

Postoperative pain rate based on VRS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190929044924N3**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

Reza Farahmandrad

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of labetalol and remifentanil on pain control after bariatric surgery

Public title

Comparative study of the effect of labetalol and remifentanil on pain control after bariatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

American Society of Anesthesiologists (ASA) class I-II-III
No contraindications and allergies to remifentanil or labetalol

Exclusion criteria:

Patients with cardiac arrhythmias Pregnant or Breastfeeding women People with a history of alcohol or drug use in the last 3 months

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

By using the randomize number table, the patients were divided into two equal groups (n=25).

Blinding (investigator's opinion)

Double blinded

Blinding description

Both drugs are injectable, and the time of injection is during anesthesia. Therefore, patients in both groups are not aware of the type of drug. The outcome assessor is also unaware of how the drug is randomly assigned.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat high way

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tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.IUMS.FMD.REC.1400.201

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

Postoperative pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain severity

Timepoint

Upon entering recovery, 2, 4, 6 and 12 hours after surgery

Method of measurement

Verbal Ranking Scale (VRS)

Secondary outcomes

empty

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

Intervention group: Lactalol group: In labetalol group, 5 mg / ml of labetalol will be injected to patients before surgical incision.

Category

Treatment - Drugs

2**Description**

Intervention group: Remifentanil group: In remifentanil group, 1 microgram / kg will be injected to patients before surgical incision.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram Hospital

Full name of responsible person

Reza Farahmand Rad

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Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyad Abbas Motavalian

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Reza Farahmandrad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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

We have not made a decision yet

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

En All individual data of the participants in this study will be shared after unidentifiable individuals.

When the data will become available and for how long

The access period will start from 1401 to 1402

To whom data/document is available

Data will be available to researchers working in the university.

Under which criteria data/document could be used

Just for performing research

From where data/document is obtainable

Refer to the person in charge to access the data.

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

The data will be available one month after the responsible person's approval.

Comments