Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 80-18 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 judges 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

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Iran (Islamic Republic of)

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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
City
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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Sponsors / Funding sources

1

Sponsor

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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
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Reza Farahmandrad
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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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