Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

investigating the effect of dexmedetomidine and remifentanil on Postoperative nausea and vomiting after laparoscopic bariatric surgery.

Protocol summary

Study aim
In this study, we've compared the effect of dexmedetomidine and remifentanil in Postoperative nausea and vomiting after laparoscopic bariatric surgery.

Design
double-blind and randomized clinical trial

Settings and conduct
Eligible Patients are randomly divided into two groups for Anesthetizing. Anesthesia induction for all patients will be applied by propofol, sufentanil, atracurium, lidocaine, dexamethasone. For maintaining anesthesia, patients are divided into two groups, A and B. each patient of one group receives a dosage of 0.1 µg per kilogram per hour plus propofol. Patients of another group receive Remifentanil 0.2 micrograms per kilogram per hour plus propofol. The secretary uses a check list, marked with the letter "A" or "B" on the patient's file and occasionally update it. However, the patient and the researcher are not aware of the prescribed medicine for the patient. only the secretary is aware of the prescribed medicine for each group. Then, PONV and the need to anti-nausea medicine are measured at 2, 4, 12, and 24 hours after the surgery. The selection for checking and examination time is based on the half-life of the medicines. .

Participants/Inclusion and exclusion criteria
femails18-5- yaers candidate for bariatric surgery< nonsmoker

Intervention groups
Eligible Patients are randomly divided into two groups for Anesthetizing. For maintaining anesthesia, patients are divided into two groups, A and B. each patient of one group receives a dosage of 0.1 µg per kilogram per hour plus propofol. Patients of another group receive Remifentanil 0.2 micrograms per kilogram per hour plus propofol.

Main outcome variables
Postoperative nausea and vomiting (PONV)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160903029656N2**
Registration date: **2019-10-01, 1398/07/09**
Registration timing: **retrospective**

Last update: **2019-10-01, 1398/07/09**
Update count: **0**

Registration date
2019-10-01, 1398/07/09

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44147550
Email address
p.delavar@shahed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
2018-01-21, 1396/11/01

Actual recruitment end date
2018-07-22, 1397/04/31

Trial completion date
2018-07-22, 1397/04/31

Scientific title
investigating the effect of dexmedetomidine and

remifentanil on Postoperative nausea and vomiting after laparoscopic bariatric surgery.

Public title
investigating the effect of dexmedetomidine and remifentanil on Postoperative nausea and vomiting after laparoscopic bariatric surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
female 18-50 y undergoing Bariatric Surgery

Exclusion criteria:
Smoking having motion sickness having surgical complications having the experience of an operation with a duration of one and a half hours or more

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Actual sample size reached: **174**

Randomization (investigator's opinion)
Randomized

Randomization description
The target population of obese patients referred to Shahid Mostafa Khomeini Hospital in Tehran, who underwent laparoscopic obesity surgery during 6 months. Of the obesity surgeries performed during this period, which was approximately 400 cases, according to the Kakarn Table, the sample size was estimated at 174.86 patients were in intervention group A and 86 patients in group B received anesthetic drug based on random numbers table.

Blinding (investigator's opinion)
Double blinded

Blinding description
After obtaining consent from the patient and entering to the operating room Patients are randomly assigned to Group A or B the secretary will mark the type of medicine used in the checklist in Group A and B patient and researcher evaluating postoperative nausea and vomiting doesn't have information about the drug used in the groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahed University

Street address
Shahid Mostafa Khomeini Hospital, Italia St, Felestin Sq

City
Tehran

Province
Tehran

Postal code
1416643491

Approval date
2018-01-15, 1396/10/25

Ethics committee reference number
IR.Shahed.REC.1396.84

Health conditions studied

1

Description of health condition studied
post operative nausea and vomiting after bariatric surgery

ICD-10 code
E66.0

ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
prevalence of post operative nausea and vomiting after laparoscopic bariatric surgery

Timepoint
Evaluation of nausea and vomiting at 2, 4, 6, 12 and 24 hours after surgery

Method of measurement
Completion of checklists based on patient reports

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexmedetomedine (alpha 2 agonist) infused at a rate of 1 µg / kg body weight per hour during maintenance of anesthesia (60 to 90 minutes), vial 200

µg Precedex made in Germany

Category

Treatment - Drugs

2

Description

Control group: Routine infusion of Remifentanil (opioid), 2 µg / kg body weight during maintenance of anesthesia (60 to 90 minutes), 1 g vial made in Spain

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mostafa Khomeini Hospital

Full name of responsible person
Delavar Parvin

Street address
Italia st., Felestin sq.

City
Tehran

Province
Tehran

Postal code
1416643491

Phone
+98 21 8895 6905

Fax
+98 21 8896 3739

Email
dr.pdelavar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
Zahra Kiasalari

Street address
Italia st., Felestin sq.

City
Tehran

Province
Tehran

Postal code
1416643491

Phone
+98 21 8895 6905

Fax
+98 21 8896 3739

Email
dr.pdelavar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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
Shahed University

Full name of responsible person
Delavar Parvin

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Italia st., Felestin sq.

City
Tehran

Province
Tehran

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Email
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Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Delavar Parvin
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Italia st., Felestin sq
City
Tehran
Province
Tehran
Postal code
1416643491
Phone
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dr.pdelavar@gmail.com

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
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available