# 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

**Postal code**
1416643491

**Phone**
+98 21 8895 6905

**Fax**
+98 21 8896 3739

**Email**
dr.pdelavar@gmail.com

## Person responsible for scientific 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
**Postal code**
1416643491
**Phone**
+98 21 8895 6905
**Fax**
+98 21 8896 3739
**Email**
dr.pdelavar@gmail.com

## 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**
+98 21 8895 6905
**Fax**
+98 21 8896 3739
**Email**
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