

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Preventive effect of Ketamine or Dexmedetomidine in the control of postoperative pain after Laparoscopic Gastric Bypass Surgery

#### Protocol summary

##### Study aim

The Preventive Effect of Administration of Dexmedetomidine or Ketamine in the Control of Postoperative Gastroparesis Laparoscopic Surgery

##### Design

three arm parallel groups, double blinded, randomized controlled trial

##### Settings and conduct

Double-blinded study, intervention groups were not aware of the placement of the groups as well as those who participated in the gathering of information, will not be inform about the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18 and under 50 years old; Body mass index greater than 35; Patients with grade 1 or 2 ASA; Non-development of neurological disorders; Exit criteria: Drug allergy; Blood pressure less than 90 mm Hg; A disease that is difficult to detect;

##### Intervention groups

The first group consists of 40 patients who will receive 1 mg / kg of ketamine 10 minutes before anesthesia induction. The second group will consist of 40 patients who receive 0.5 mg / kg of Dexmedetomidine for 10 minutes before anesthesia induction. The control group will include 40 people who will not receive any of the previous treatments.

##### Main outcome variables

Patient's pain during recovery using VAS measurement.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130311012782N29**

Registration date: **2019-05-01, 1398/02/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-05-01, 1398/02/11**

Update count: **0**

##### Registration date

2019-05-01, 1398/02/11

##### Registrant information

###### Name

Ali Mehrabi kushki

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3629 1510

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mehrabi@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-30, 1398/02/10

##### Expected recruitment end date

2019-05-31, 1398/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Preventive effect of Ketamine or Dexmedetomidine in the control of postoperative pain after Laparoscopic Gastric Bypass Surgery

##### Public title

Preventive effect of Ketamine or Dexmedetomidine in the control of postoperative pain after Laparoscopic Gastric Bypass Surgery

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Aged 18 and under 50 years old Body mass index greater than 35 Patients with ASA grade 1 or 2 Lack of neurological disorders. Lack of heart disease or lung disease No addiction

**Exclusion criteria:**  
drug reaction Blood pressure less than 90 mm Hg patient who Intubated hard

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization method: Randomization block, randomization unit: Individual, Random layer: not done Randomization, tool: Random sequence generation software (Excel), How to create random sequence: Using random blocks, each block contains 4 people And assign a number from 1 to 6 to each block

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients will not be aware of being in the study groups and collecting data will be done by people who are unaware of the groupings.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Isfahan University of Medical sciences

**Street address**  
Isfahan university of medical sciences, azadi square, Isfahan, Iran

**City**  
Isfahan

**Province**

Isfahan

**Postal code**  
81746-73461

**Approval date**  
2017-03-08, 1395/12/18

**Ethics committee reference number**  
IR.MUI.REC.1396.234

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

R52

#### ICD-10 code description

Pain, unspecified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Every 15 minutes until the patient leaves the recovery and in the department at 6, 12, 18, and 24 hours

#### Method of measurement

Using the VAS Rating Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: 1 mg per kg of ketamine 10 minutes before induction of anesthesia will be given.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: 0.5 mg per kg of Dexmedetomidine 10 minutes before induction of anesthesia will be given.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: None of the drugs and treatments of other groups will be received

#### Category

Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Al Zahra Hospital

**Full name of responsible person**

Dr Seyed Taghi Hashemi

**Street address**

Alzahra hospital, Alzahra street, Isfahan, Iran

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr Shaghayegh haghjoo Javanmard

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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**

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**

Ali Mehrabi Koushki

**Position**

Responsible for research/Master of Science

**Latest degree**

Master

**Other areas of specialty/work**

Medical Education

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Dr. Seyed Taghi Hashemi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

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Resident

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Medical doctor

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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 will be shared

**When the data will become available and for how long**

Immediately after the publication of the article

**To whom data/document is available**

People who need this information

**Under which criteria data/document could be used**

All uses are allowed

**From where data/document is obtainable**

Contact with corresponding author

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

using Email

**Comments**