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
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Name of organization / entity
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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

Isfehan

Province

Isfehan

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
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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
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
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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