

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the effect of intraperitoneal ropivacaine with the combination of ropivacaine and dexmedetomidine in reducing pain after sleeve gastrectomy

Protocol summary

Study aim

Comparison of the effect of intraperitoneal ropivacaine with the combination of ropivacaine and dexmedetomidine in reducing pain after sleeve gastrectomy

Design

Randomized controlled clinical trial with parallel groups, double-blind, phase 3 on 48 patients. Randomization will be done by block method and using the sequence provided by Random Generator software.

Settings and conduct

This clinical trial will be conducted on eligible patients in the general operating room of Sina Hospital (Tehran University of Medical Sciences). Eligible patients are randomly assigned to one of the study groups and receive the desired intervention. The intensity of pain, nausea and vomiting after anesthesia and the dose of narcotic required for recovery will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient is a candidate for bariatric laparoscopic surgery; The patient's age is over 18 years; The patient is classified as ASA class 1 to 3 according to the American Society of Anesthesiologists. Exclusion criteria: The patient has an opioid addiction; The patient has a previous history of abdominal surgery; The patient has a history of allergy to any of the drugs under study.

Intervention groups

After the completion of the surgical incision and before the removal of the surgical trocar, it is sprayed intraperitoneally in the area of the esophageal hiatus and the gastric surgical incision within two minutes, according to the type of the desired intervention group. Intervention group 1: (ropivacaine 0.5% 20ml + normal saline up to the final volume of 40ml), intraperitoneally Intervention group 2: (ropivacaine 0.5% 20 ml + dexmedetomidine 1 µg/kg + normal saline up to the final

volume of 40 ml), intraperitoneally Control group: normal saline 40ml, intraperitoneally

Main outcome variables

Pain intensity based on the VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151221025641N6**

Registration date: **2023-03-30, 1402/01/10**

Registration timing: **prospective**

Last update: **2023-03-30, 1402/01/10**

Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Parisa Kianpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2660 2854

Email address

pk.pioneer1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of intraperitoneal ropivacaine with the combination of ropivacaine and dexmedetomidine in reducing pain after sleeve gastrectomy

Public title
Comparison of the effect of intraperitoneal ropivacaine with the combination of ropivacaine and dexmedetomidine in reducing pain after sleeve gastrectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient is a candidate for bariatric laparoscopic surgery; The patient's age is over 18 years; The patient is classified as ASA class 1 to 3 according to the American Society of Anesthesiologists;
Exclusion criteria:
The patient has an opioid addiction; The patient has a previous history of abdominal surgery; The patient has a history of allergy to any of the drugs under study.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the block method and 6 blocks including the intervention and control groups will be used. The preparation of randomization sequences is done using the Random Generator software, and the created sequences will be available to a trained staff person who is not a member of the research group, and other people will be unaware of the sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patient and the researchers are unaware of the type of analgesic intervention received during surgery. A trained staff (anesthetist) who is not a member of the research group will prepare the medicinal solution according to the randomization sequence and will be provided to the researcher.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Central building, Ghods St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1913914435
Approval date
2022-05-31, 1401/03/10
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1401.023

Health conditions studied

1

Description of health condition studied
Sleeve gastrectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity
Timepoint
On 0,2,4,8,12,24 hours
Method of measurement
VAS scale

Secondary outcomes

1

Description
Opioid dosage requirement
Timepoint
On 0,2,4,8,12,24 hours
Method of measurement
Medical record

2

Description

Post anesthetic nausea and vomiting

Timepoint

On 0,2,4,8,12,24 hours

Method of measurement

Patient examination

Intervention groups

1

Description

Intervention group: ropivacaine 0.5% 20ml + normal saline up to the final volume of 40ml, intraperitoneally

Category

Treatment - Drugs

2

Description

Intervention group: ropivacaine 0.5% 20 ml + dexmedetomidine 1 µg/kg + normal saline up to the final volume of 40 ml, intraperitoneally

Category

Treatment - Drugs

3

Description

Control group: normal saline 40ml,intraperitoneally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mohammadreza Neishaboury

Street address

Sina hospital; Hasan abad Sq., Imam Khomeini Ave.

City

Tehran

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4691111367

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Email

mrneishaboury@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central building, Ghods Ave., Keshavarz Blvd.

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vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

30

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

2

Sponsor

Name of organization / entity

Anesthesiology, critical care and pain management research center

Full name of responsible person

Farhad Etezadi

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Sina hospital, Hasan abad sq., Imam khomeini Ave.

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accpm.rc.tums@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Anesthesiology, critical care and pain management research center

Proportion provided by this source

70

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**

Tehran University of Medical Sciences

Full name of responsible person

Samira Shokri

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sina hospital, Hasan abad sq., Imam Khomeini Ave.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Neishaboury

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Samira Shokri

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available