

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of interapitonal bupivacaine on postoperative pain in laparoscopic bariatric surgery

Protocol summary

Study aim

Aim: The effect of intrapritoneal bupivacaine on postoperative pain in laparoscopic bariatric surgery.

Design

Design: a randomized, Double-blind, single-center, phase II clinical trial.

Settings and conduct

Patients undergoing laparoscopic bariatric(sleeve, bypass, minibypass) surgery are divided into two groups: bupivacaine and normal saline for washing the cutting sites and anastomosis. Pain score will be recorded during the first 24 hours of operation.

Participants/Inclusion and exclusion criteria

The main inclusion criteria included patients undergoing laparoscopic bariatric surgery with age 17-60 years with BMI>40 and ASA 2. Exclusion criteria included patients with a history of analgesics (narcotic or non-narcotic) 24 hours before surgery.

Intervention groups

Patients were divided into two groups bupivacaine and normal saline.

Main outcome variables

The main outcome variables: Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140109016151N6**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of interapitonal bupivacaine on postoperative pain in laparoscopic bariatric surgery

Public title

effect of interapitonal bupivacaine on postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: patients undergoing laparoscopic bariatric surgery with BMI>40 . With age 17-60 years. ASA 2.

Exclusion criteria:

Exclusion criteria: patients with history of analgesics

(narcotic or non-narcotic) 24 hours before surgery. Drug or alcohol abuse or allergy to any of the drugs used in the study. Chronic pain syndrome.

Age

From **17 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, individual, sealed envelopes, coin flipping

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, principle investigator and healthcare providers (Physicians, nurses) The person who visits the patients postop, does not have the slightest idea of whether the patient belongs to case or control groups and merely records the postop pain and opioid used for each patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

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Postal code

1449614535

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411174017

Health conditions studied

1

Description of health condition studied

Morbid Obesity

ICD-10 code

E66.8

ICD-10 code description

Other obesity

Primary outcomes

1

Description

pain

Timepoint

2, 8 and 24 hours after surgery

Method of measurement

based on a visual scale VAS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 cc of 0.2% bupivacaine is prescribed.

Category

Prevention

2

Description

Control group: 50 cc normal saline is prescribed.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar Hospital

Full name of responsible person

Dr. Alireza Pournajafian

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Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Dr. Alireza Pournajafian

Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Resident of Anesthesia

Latest degree

Medical doctor

Other areas of specialty/work**Street address**

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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