

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The evaluation of effect of adding dexmedetomidine to bupivacaine on the block in laparotomy surgery

Protocol summary

Summary

The aim of this study is the evaluation of effect of adding dexmedetomidine to bupivacaine on the block in laparotomy surgery. 42 patients undergoing laparotomy referred to Hazrat Rasoul Hospital as a randomized, double-blind, without placebo and without control phase 1-2 trials using random numbers and the method of random block by block 6 each to two groups are divided. Patients must be over 20 years and ASA have one to three patients with intraoperative hemodynamic disturbances, disturbances in consciousness, mechanical ventilation in the postoperative and need to continue after the end of anesthesia is excluded. In the first group, in the block site, bupivacaine and dexmedetomidine is injected but only bupivacaine is injected in the second group. The outcome after surgery, total drug intake after surgery, patient satisfaction and complications in each group is determined and compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121212642N23**

Registration date: **2015-12-27, 1394/10/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-27, 1394/10/06

Registrant information

Name

Majid Golestani Eraghi

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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dr.golestani@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-03-30, 1394/01/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effect of adding dexmedetomidine to bupivacaine on the block in laparotomy surgery

Public title

The effect of adding dexmedetomidine to bupivacaine in paravertebral block.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA I-III; there is no known sensitivity or contraindications for injection of studied drugs; non-prescription tranquilizer in the 24 hours prior to anesthesia; no history of chronic use of opioids or benzodiazepines; no history of liver disease; no history of cardiovascular disease; no history of lung disease; lack the urgency of the surgery. Exclusion criteria: Those who find complicated surgery for any reason; intraoperative

hemodynamic disturbances; disturbances in consciousness in the post-operative stage; need to continue mechanical ventilation after the end of anesthesia; complications related to surgery.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomisation is performed with using random numbers and the method of random blocks by block 6.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway

City

Tehran

Postal code

Approval date

2014-10-21, 1393/07/29

Ethics committee reference number

933389 /105/3

Health conditions studied

1

Description of health condition studied

nerve Block

ICD-10 code

Y48.3

ICD-10 code description

adverse of therapeutic use

Primary outcomes

1

Description

Amount of narcotic of injection

Timepoint

In times of 2, 6, 12, 24 and 48 hours after surgery

Method of measurement

The based on question of the floor nurses and based on milligram

2

Description

Amount of pain

Timepoint

In times of 2, 6, 12, 24 and 48 hours after surgery

Method of measurement

Based on patient state and show the related shaped VAS ruler

Secondary outcomes

1

Description

Amount of Satisfaction

Timepoint

In times of 2, 6, 12, 24 and 48 hours after surgery

Method of measurement

According to the questionnaire, as excellent, good, average, unhappy

Intervention groups

1

Description

In the first group (intervention group) after general anesthesia and completion of the operation, the block identified by ultrasound and bupivacaine 0.25% with a volume of 20 cc with a dose of 100 microgram dexmedetomidine is injected.

Category

Treatment - Other

2

Description

In the second group (control group) after general anesthesia and completion of the operation, the block identified by ultrasound and bupivacaine 0.25% with a volume of 20 cc without dexmedetomidine is injected.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Hospital

Full name of responsible person

Farnad Imani

Street address

Hazrat Rasool Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyed Alijavad Musavi

Street address

Vice chancellor for research of Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Anesthesiology group of Iran University of Medical Science

Full name of responsible person

Farnad Imani

Position

Fellowship of pain

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Anesthesiology group of Shahid beheshti University of Medical Sciences

Full name of responsible person

Majid Golestani Eraghi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Darabad Ave

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty