Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 isl be 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 be 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
+98 21 3336 0547
Email address
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/د

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
Street address
Hazrat Rasool Hospital, Satarkhan Ave
City
Tehran
Postal code
Phone
+98 21 6651 5001
Fax
Email
Farimani@iums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Hazrat Rasool Hospital, Satarkhan Ave
City
Tehran
Postal code
Phone
+98 21 6651 5001
Fax
Email
farimani@iums.ac.ir
Web page address

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
City
Tehran
Postal code
Phone
+98 21 2712 2525
Fax
Email
dr.golestani@sbmu.ac.ir
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