Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the effect of injecting Bupivacaine alone and in association with dexmedetomidine through transversus abdominis plane (TAP) block with ultrasound-guided on pain and complications after inguinal hernia surgery: A randomized controlled clinical trial

Protocol summary

Study aim

In case of the effectiveness of injecting bupivacaine alone and in combination with dexmedetomidine via transverse abdominis plane (TAP) block under ultrasound guidance for post-operative pain control in inguinal hernia surgery, this method can be used to reduce postoperative pain in this group of patients. Thereby, helping patients to get out of the bed faster and subsequently reducing hospital stay and reducing medical costs.

Design

The present study is a double-blind, randomized controlled clinical trial of 66 patients with elective inguinal hernia surgery with an average age of 18 to 65 years and ASA class I and II. A Clinical trial with control group, with parallel groups, double-blind and randomized

Settings and conduct

Razi Hospital Rasht

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 65 years old Body mass index 35-18 Kilograms per square meter Lack of drug sensitivity, No alcohol and drug addiction Type of surgery including restoration without tension with mesh ASA class I, II exclusion criteria: Surgery lasts more than 2 hours Need for another surgical procedure during inguinal hernia surgery Need to get opium in the recovery room Excessive hemorrhage Recurrence of hernia And need for spinal anesthesia

Intervention groups

Injecting bupivacaine in combination with dexmedetomidine via transverse abdominis plane (TAP) block with ultrasound guidance on pain and complications after inguinal hernia surgery

Main outcome variables

Pain control

General information

Reason for update

Acronym

TAP Block

IRCT registration information

IRCT registration number: **IRCT20121216011766N5**
Registration date: **2019-04-21, 1398/02/01**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-21, 1398/02/01**
Update count: **0**

Registration date

2019-04-21, 1398/02/01

Registrant information

Name

Hossein Khoshrang

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 0028

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of injecting Bupivacaine alone and in association with dexmedetomidine through transversus abdominis plane (TAP) block with ultrasound-guided on pain and complications after inguinal hernia surgery: A randomized controlled clinical trial

Public title

Comparison of the effect of bupivacaine injection alone and in association with dexmedetomidine on pain and complications after inguinal hernia surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 65 years old Body mass index 35-18 kilogram / meter 2 Lack of drug sensitivity No alcohol and drug addiction Type of surgery including restoration without tension with mesh ASA class I,II

Exclusion criteria:

Surgery lasts more than 2 hours Need for concurrent surgery during inguinal hernia surgery Need to get opium in recovery room excessive hemorrhage Recurrence of hernia Need for spinal anesthesia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients eligible for inclusion will be divided into 2 groups using the Blocked Randomization method. One of the nurses of the relevant ward, who is not aware of the implementation of the study will divide the patients into two groups of 33 marked as I and C as the intervention group and control group. Random sequences will be generated using the Random Generator program. Based on the random block method, 15 blocks of four-block and one six-block will be generated for 66 patients. After producing the list, each person will be assigned a dedicated code and will be recognized by this code during the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients eligible for inclusion will be divided into 2 groups of 33 patients marked as I and C (intervention and control group) using the Blocked Randomization method, by One of the nurses of the relevant ward, who is not aware of the implementation of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences and Health Services

Street address

Shahid Beheshti Highway

City

Rasht

Province

Guilan

Postal code

4193833697

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.GUMS.REC.1397.449

Health conditions studied

1

Description of health condition studied

Transversus abdominis plane (TAP) block with ultrasound guidance on pain and complications after inguinal hernia surgery

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes

1

Description

Comparing the effect of injecting Bupivacaine alone and in association with dexmedetomidine through Transversus Abdominis Plane(TAP) Block with ultrasound guidance in pain and complications after inguinal hernia surgery

Timepoint

In the recovery unit (at 0 o'clock) and at 2, 4, 6, 12, 24 hours after surgery, pain intensity will be measured in the two groups with visual analogue scale (VAS).

Method of measurement

In this way, people are asked to show their pain intensity on a 10 cm ruler. no pain will be scored as zero and

score 10 is for the highest pain.

Secondary outcomes

1

Description
In 24 hours after surgery that patients are hospitalized in ward , they will be prescribed 0.5 milligram/kilogram of pethidine, if they need painkillers and they state VAS> 3. Also, complications such as nausea, dizziness and vomiting, the first dose and the mean dose of pethidine consumed in the two groups will be investigated.
Timepoint
In the recovery unit (at 0 o'clock) and at 2, 4, 6, 12, 24 hours after surgery
Method of measurement
Nausea, dizziness and vomiting

Intervention groups

1

Description
Intervention group:20 milliliters of bupivacaine 0.5% with 1 milliliter (100 micrograms) of dexmedmotidine (Precedex brand containing 200 microgram / 2 milliliter of drug, HOSPIRA manufacturer reference of the United States of America)
Category
Treatment - Drugs

2

Description
Control group: 20 milliliter bupivacaine 0.5% plus 1 milliliter normal saline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital Rasht
Full name of responsible person
DR Hossein Khoshang
Street address
Sardar jungal Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht 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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Hoseein Khoshrang
Position
Anesthesiologist
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
The results of the research will be publicly available without mentioning the participants' names in the form of a research paper

When the data will become available and for how long
As soon as the article is published, the information will be publicly available in the general format

To whom data/document is available
researchers

Under which criteria data/document could be used
To do research

From where data/document is obtainable
Contact the relevant journal site or email and contact the responsible author

What processes are involved for a request to access data/document
Contact the relevant journal site or email and contact the responsible author

Comments