Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparing the analgesic efficacy of adding different doses of dexmedetomidine to bupivacaine in ultrasound-guided Transversus Abdominis Plane (TAP) block in patients undergoing open inguinal herniorraphy

Protocol summary

Study aim
This study aims to compare the analgesic efficacy of adding different doses of dexmedetomidine to bupivacaine in ultrasound-guided Transversus Abdominis Plane (TAP) block in patients undergoing open inguinal herniorrhaphy

Design
A double-blind, randomized, phase 3 clinical trial with 3 parallel arms. Each group will contain at least 25 participants (totaling 75 participants).

Settings and conduct
In this study, participants will be assigned to three study groups randomly. The injection will be ultrasound-guided TAP block under the sterile condition and the injection solution is according to their study group. The patient's pain will be assessed 2, 4, 8, 12, and 24 hours after the end of surgery by the use of Visual Analogue Pain Scale. The first time patient needs analgesic will also be recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Undergoing open inguinal herniorrhaphy Signing the informed consent form Age between 18 - 75 years Class 1 or Class 2 according to American Society of Anesthesiologists (ASA) classification. Exclusion criteria: History of substance abuse Presence of pain in the operation site History of psychological disorders History of hypertension or anti-hypertensive medication History of heart disease (Ischemic, Heart valve disease, heart blocks) History of kidney failure History of hypersensitivity to the medications intended to be used in the study Being illiterate or having difficulty understanding Visual Analogue Pain Scale

Intervention groups
There are 3 groups in this study. The injectable solution in each group is 19ml of Bupivacaine combined with dexmedetomidine solution in 1 ml normal Saline with the following concentration: The first group, 0.5 mcg/kg dexmedetomidine. The second group, 1 mcg/kg dexmedetomidine. The third group,1.5 mcg/kg dexmedetomidine.

Main outcome variables
Reported pain level. Complications and side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190421043336N1**
Registration date: **2019-09-18, 1398/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-18, 1398/06/27**
Update count: **0**

Registration date
2019-09-18, 1398/06/27

Registrant information

Name
Gilda Talebi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01
Expected recruitment end date
2020-07-22, 1399/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the analgesic efficacy of adding different doses of dexmedetomidine to bupivacaine in ultrasound-guided Transversus Abdominis Plane (TAP) block in patients undergoing open inguinal hernioraphy

Public title
Analgesic efficacy of dexmedetomidine in patients undergoing inguinal hernioraphy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Signing the informed consent by the patient Age between 18 - 75 years Class 1 or Class 2 according to American Society of Anesthesiologists (ASA) physical status classification
Exclusion criteria:
History of substance abuse Presence of pain in the operation site before surgery History of psychological disorders History of high blood pressure or history of anti-hypertensive medication History of heart disease (Ischemic Heart disease, Heart valve disease, heart blocks) History of kidney failure History of hypersensitivity to the medications intended to be used in the study Being illiterate or lacking the capacity to understand Visual Analogue Pain Scale
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization works by randomizing participants within blocks such that an equal number are assigned to each treatment. In this study we randomly assign the patients to 6 separate blocks (with equal numbers) and perform the first type of treatment (0.5 mcg/kg dexmedetomidine) on the blocks 1 and 4, the second type of treatment (1 mcg/kg dexmedetomidine) on the blocks 2 and 5, and the third type of treatment (1.5 mcg/kg dexmedetomidine) on the blocks 3 and 6. To achieve the necessary power for the study, each block has at least 13 patients (at least 78 patients total).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind clinical trial, although the patients will be aware of the type of medication that being used for them, they will not know what strength will be used for them. The anesthesiologist will perform the injection according to the patients corresponding treatment group. The questionnaire for evaluating the effectiveness of the treatment will be filled by an anesthesiology resident who is not aware of the patients treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences
Street address
Deputy of Research and Technology of Kurdistan University of Medical Sciences, Pasdaran Boulevard
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Approval date
2019-03-16, 1397/12/25
Ethics committee reference number
IR.MUK.REC.1397.382

Health conditions studied

1

Description of health condition studied
Inguinal hernia
ICD-10 code
K40
ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
The patient's pain level, assessed by the use of Visual Analogue Pain Scale
Timepoint
At 2, 4, 8, 12, and 24 hours after the end of surgery
Method of measurement
Visual Analogue Pain Scale

2

Description
The first time patient needs analgesic
Timepoint
The first time patient asks for analgesic after the end of surgery
Method of measurement
Number of hours between end of surgery and the first time patient asks for analgesic

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The injectable solution is 19ml of Bupivacaine combined with 0.5 mcg/kg dexmedetomidine solution in 1 ml normal Saline.
Category
Treatment - Drugs

2

Description
Intervention group: The injectable solution is 19ml of Bupivacaine combined with 1 mcg/kg dexmedetomidine solution in 1 ml normal Saline.
Category
Treatment - Drugs

3

Description
Intervention group: The injectable solution is 19ml of Bupivacaine combined with 1.5 mcg/kg dexmedetomidine solution in 1 ml normal Saline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Karim Naseri
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Sponsors / Funding sources

1

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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
Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person
Karim Naseri

Position
Associate Professor

Latest degree
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Other areas of specialty/work
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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