Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of preemptive subcutaneous infiltration of dexmedetomidine-bupivacaine combination with ketamine-bupivacaine combination on pain after lower abdominal surgeries

Protocol summary

Study aim

comparson the effect of preemptive infiltration of dexmedetomidine bupivacaine combination with ketaminebupivacaine combination on pain after lower abdominal surgeries

Design

In this triple blind randomized controlled clinical trial of phase 3, 90 patients candidates for lower abdominal surgery by random allocation method in three groups of 30 people randomly allocated in the 3 group of dexmedetomidinebupivacaine combination, in the second group ketaminebupivacaine and in the second group Third, normal saline is injected and the results are compared in three groups.Randomization of patients is done using Random Allocation Software.

Settings and conduct

This thrple blind randomized controlled clinical trial study (patients, data collector and statistical analyst) will be done in 1 Al-Zahra and Kashani hospitals of Isfahan during 2023. The three group, received 40 ml of bupivacaine 25% plus dexmedetomidine 1.5 µg/kg, 40 ml of bupivacaine 25% plus ketamine 2 µg/kg, and 40 ml of normal saline.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) patient candidates for lower abdominal surgery, 2) age range of 18-65 years old Exclusion criteria: 1)drug addiction, 2) history of drug allergies, 3) history of psychological problems

Intervention groups

Group 1: Before surgical incision, 40 cc of bupivacaine 0.25% in combination with dexmedetomidine 1.5 µg/kg will be received. It is injected in the form of infiltration at the site of the surgical incision.Group 2: Before surgical incision, 40cc of bupivacaine 0.25% in combination with ketamine 2µg/kg will be given. It is injected in the form of infiltration at the site of the surgical incision.Group 3: Before surgical incision, 40 cc of normal saline is injected as infiltration in the surgical incision site.

Main outcome variables

Severity of postoperative pain, the first time to receive analgesia and dose of analgesi received

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090129001615N9**
Registration date: **2023-12-02, 1402/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-02, 1402/09/11**
Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name
Azim Honarmand
Name of organization / entity
Alzahra hospital
Country
Iran (Islamic Republic of)
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+98 31 3668 0048
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honarmand@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-03-14, 1402/12/24

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of preemptive subcutaneous infiltration of dexmedetomidine-bupivacaine combination with ketamine-bupivacaine combination on pain after lower abdominal surgeries

Public title
The effect of combination of dexmedetomidine-bupivacaine with ketamine-bupivacaine on post poerative pain after lower abdominal surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
atients who are candidates for elective lower abdominal surgery Age range 18-65 years ASA 1 or 2
Exclusion criteria:
Patients with a history of allergy to the studied drugs (dexmedetomidine, ropivacaine, and ketamine) Patients with a history of drug addiction Patients with mental health problems Obese patients weighing more than 100 kg Patients with inability to express pain intensity based on VAS criteria Infection at the surgical incision site Any change in anesthesia method
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done Random Allocation software. In this soft ware , the total number of samples and the number of groups are entered into the software. The output of the software is a list including three groups A, B and C, which has randomly distributed patients by number among the three groups. According to the mentioned list, patients are divided into three groups according to the time of entering the operating room, so that the sample volume reaches the required number in each group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The injected drug are prepared by the researcher and injected to the patients. The patients, the person collecting the drugs and the person analyzing the data will be unaware of the type of drug combination injected to the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib Street
City
Isfahana
Province
Isfehan
Postal code
8434193474
Approval date
2022-11-15, 1401/08/24
Ethics committee reference number
IR.MUI.MED.REC.1401.384

Health conditions studied

1

Description of health condition studied
anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
post operatie pane
Timepoint
Every 15 minutes during recovery and at 2, 6, 12 and 24 hours after the operation
Method of measurement
With using vigual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: recipient of 40 cc bupivacaine 0.25% (made by Exir institutein) combination with dexmedetomidine 1.5 µg/kg (made by Imozhen institute) before surgical incision
Category
Treatment - Drugs

2

Description
Intervention group2: recipient of 40 cc bupivacaine 0.25% (made by Exir institutein) in combination with ketamine 2µg/kg(made by Rutex institute)
Category
Treatment - Drugs

3

Description
Control group: recipient of 40 cc of normal saline(made by Razi institute) as infiltration at the surgical incision site
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Mahdieh Bazrafshan
Street address
Sofeh street
City
Isfahan
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2

Recruitment center
Name of recruitment center
kashani hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
gholamreza Askari
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Ali Mehrabi Koushki
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The plan belongs to the government organization and it is not possible to share it
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available