

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

comparison 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)

Phone

+98 31 3668 0048

Email address

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 postoperative pain after lower abdominal surgeries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients 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 software, 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

Isfahan

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 operative pain

Timepoint

Every 15 minutes during recovery and at 2, 6, 12 and 24 hours after the operation

Method of measurement

With using visual 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

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2

Recruitment center

Name of recruitment center

kashani hospital

Full name of responsible person

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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

Position

statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

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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