

# 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

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

Isfahan

#### Province

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#### Postal code

8434193474

#### Phone

+98 31 3668 2174

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hkaveh57@gmail.com

## 2

### Recruitment center

#### Name of recruitment center

kashani hospital

#### Full name of responsible person

Mahdieh Bazrafshan

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Ayatollah Kashani street

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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

#### Street address

Hezar Jerib street

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gh\_askari@med.mui.ac.ir

#### 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 scientific inquiries

### Contact

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Esfahan University of Medical Sciences  
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professor  
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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