Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of two medicinal combinations Ropivacaine-Dexmedetomidine and Ropivacaine-Ketamine by subcutaneous method in controlling postoperative pain in patients with Inguinal hernia candidates

Protocol summary

Study aim

Comparison of the effect of two medicinal combinations ropivacaine-dexmedetomidine and ropivacaine-ketamine by subcutaneous method in controlling postoperative pain in patients with inguinal hernia candidates

Design

The present study is a clinical trial, with parallel groups, randomized (using block randomization), phase 3 on 140 patients.

Settings and conduct

In this double-blind randomized clinical trial, patients who are candidates for inguinal hernia surgery referred to Waliasr Hospital in Arak will be divided into two identical groups: dexmedetomidine + ropivacaine and ketamine + ropivacaine. In this study, the patients (by the label on the syringe) and the outcome assessor (by coding the patients) will be blinded. In each group, drug treatment will be prescribed subcutaneously before surgery. Finally, two groups will be evaluated in terms of study results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for inguinal hernia surgery aged 18 to 65 years; body mass index below 30; Consent to participate in the study. Exclusion criteria: history of allergy to the study drugs; smoking; Underlying disease.

Intervention groups

Intervention group 1: Dexmedetomidine 1 microg/kg along with ropivacaine 0.75% (3 mg/kg) diluted until reaching the final volume of 10 cc of distilled water are received subcutaneously. Intervention group 2: 100 mg of ketamine with ropivacaine 0.75% (3 mg/kg) diluted until reaching the final volume of 10 cc of water are received subcutaneously.

Main outcome variables

Blood pressure, heart rate, complications of dizziness and headache, pain score, amount of narcotic drug used, duration of pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N23**
Registration date: **2024-08-17, 1403/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-17, 1403/05/27**
Update count: **0**

Registration date

2024-08-17, 1403/05/27

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3366 7583

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amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-18, 1403/03/29

Expected recruitment end date

2024-10-20, 1403/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of two medicinal combinations Ropivacaine-Dexmedetomidine and Ropivacaine-Ketamine by subcutaneous method in controlling postoperative pain in patients with Inguinal hernia candidates

Public title
Investigating two medicinal combinations of Ropivacaine-Dexmedetomidine and Ropivacaine-Ketamine by subcutaneous method in postoperative pain control in Inguinal hernia candidate patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidates for inguinal hernia surgery between the ages of 18 and 65 Body mass index below 30 Consent to participate in the study

Exclusion criteria:
History of allergy to studied drugs Smoking Underlying disease

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: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

Blinding (investigator's opinion)
Double blinded

Blinding description
Medicines will be in pre-drawn and labeled syringes. Therefore, the participants will not know the type of drug injected. In addition to this, the outcome evaluator (surgical assistant) does not know the type of drugs and follows up the results based on the patient's file number and will hand them over to the main supervisor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2023-12-31, 1402/10/10

Ethics committee reference number
IR.ARAKMU.REC.1402.203

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
Blood pressure

Timepoint
Every 5 minutes

Method of measurement
Pressure gauge device

2

Description
Heart rate

Timepoint
Every5 minutes

Method of measurement

Cardiac monitoring

3

Description
Complications of dizziness and headache
Timepoint
The end of the intervention
Method of measurement
Ask the patient

4

Description
Pain score
Timepoint
The amount of pain during recovery at 2, 4, 6, 12, and 24 hours after the operation.
Method of measurement
Visual Analogue Scale Ruler

5

Description
Amount of narcotic drug used
Timepoint
24 hours after surgery
Method of measurement
Patient file

6

Description
Duration of pain relief
Timepoint
After surgery
Method of measurement
Watch

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexmedetomidine 1 microgram/kg (Exir Pharmaceuticals-Iran) along with ropivacaine 0.75% (3 mg/kg) (Molteni pharmaceutical company, Italy) diluted to reach the final volume of 10 cc of distilled water are received subcutaneously.
Category
Treatment - Drugs

2

Description
Intervention group: 100 mg of ketamine (Elixir pharmaceutical company - Iran) along with ropivacaine 0.75% (3 mg/kg) (Molteni pharmaceutical company, Italy) diluted to reach the final volume of 10 cc of water will be received subcutaneously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr hospital
Full name of responsible person
Dr. Reza Shojaei
Street address
Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran
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Postal code
3814957558
Phone
+98 86 3222 2003
Email
R.shojaei@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Mehdi Salehi
Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
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salehi58@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Reza Shojaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Eqbali

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2024/11/20 to 2027/11/20 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible

persons in this study.

From where data/document is obtainable

Academic researchers and university professors can request Dr. Reza Shojaei to use the data after contacting the relevant professor via message or email. Dr. Reza Shojaei: Phone: 09123700960 Email: R.shojaei@arak.mu.ac.ir Address: Valiasr Hospital, Arak, Vice-Chancellor of Hospital Education

What processes are involved for a request to access data/document

Letter writing should be done with professors and universities.

Comments