

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation of the effect of Ketamine in comparison with Dexmedetomidine dose in pain management and postoperative complications of orthopedics

Protocol summary

Study aim

The effect of ketamine is compared with Dexmedetomidine in the management of pain and complications after orthopedic surgery of the lower extremities of the femur or pelvis.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. For randomization, the necessary software for permutation blocks is used

Settings and conduct

Patients undergoing orthopedic surgery of the femur or pelvis in Vali Asr Teaching Hospital in Arak are randomly divided into two groups. The intervention group received ketamine at a dose of 1 mg / kg and the control group received dexmedetomidine at a dose of 1 µg / kg in the pain pump after orthopedic surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years, orthopedic surgery of the lower limb or pelvis with general anesthesia, satisfaction with the research, absence of underlying diseases such as cardiovascular, physical condition 1 and 2 American Society of Anesthesiologists (ASA)) Exclusion criteria: Sensitivity to ketamine or Dexmedetomidine, cardiovascular and pulmonary disease, death of patient, dissatisfaction with participation in the study, cancellation of the study at any stage.

Intervention groups

The intervention group received ketamine at a dose of 1 mg / kg and the control group received Dexmedetomidine at a dose of 1 µg / kg in the pain pump after orthopedic surgery

Main outcome variables

Comparison of postoperative pain in patients in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161014030294N5**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Mansoreh Karimikia

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 4702

Email address

m.karimikia@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Ketamine in comparison with Dexmedetomidine dose in pain management and postoperative complications of orthopedics

Public title

Investigation of the effect of Ketamine in comparison with Dexmedetomidine dose in pain management and postoperative complications of orthopedics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years orthopedic surgery of the lower limb or pelvis with general anesthesia consent to research absence of underlying diseases such as cardiovascular physical condition 1 and 2 American Society of Anesthesiologists (ASA)

Exclusion criteria:

Hypersensitivity to Ketamine or Dexmedetomidine cardiovascular and pulmonary disease death of patient dissatisfaction with participation in the study withdrawal from the study at any stage

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done purposefully. In this study, due to the existence of two types of treatment, the block randomization method is used. Is a randomization unit of the individual. Depending on the sample size, blocks with a capacity of 4 units are considered. In order to better randomize, the web-based software is used to prepare a randomization list, which creates random permutations for each type of treatment in each block, and due to the change of permutations in each block, concealment is also observed. The researcher's ability to predict the next treatment decreases during the study. Site used for random permutation block method:

<https://www.sealedenvelope.com/simple-randomiser/v1/lits>

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who have undergone orthopedic surgery of the lower extremities of the femur or pelvis are included in the study by easy sampling. Patients are randomly

divided into two groups of 35 people. Group 1 receives a pain pump containing Ketamine labeled A and group 2 receives a pain pump containing Dexmedetomidine labeled B. The preparation of the pain pump is done by someone outside the study and the caregiver does not know the type of medicine inside the pain pump.

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

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.ARAKMU.REC.1399.256

Health conditions studied

1

Description of health condition studied

Femoral orthopedic surgery

ICD-10 code

s72

ICD-10 code description

femoral fracture

Primary outcomes

1

Description

The extent of postoperative pain

Timepoint

Pain score before the intervention and after up to 8 hours after the operation every hour

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They receive ketamine at a dose of 1 mg / kg in the pain pump after the operation. Complications and pain scores are observed before the intervention and after 8 hours after the operation in the recovery and transferred ward.

Category

Treatment - Drugs

2

Description

Control group: They receive dexmedetomidine at a rate of 1 microgram per kilogram in the pain pump after the operation. Observation of complications and pain score before the intervention and after 8 hours after the operation is performed every hour in the recovery and transferred ward.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital in Arak

Full name of responsible person

Behnam Mahmoudieh

Street address

Vali Asr Square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2004

Fax

+98 86 3223 1283

Email

Behnammahmoudye@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 6055

Fax

+98 86 3313 3147

Email

a.kamali@arakmu.ac.ir

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

Mansoreh Karimi Kia

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 6055

Email

karimikia93@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Behnam Mahmoudieh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

A'lām-Al-Hoda Street, Shahid Shiroodi Street, Arak,
Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Fax

+98 86 3313 3147

Email

Behnamahmoudye@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mansoreh Karimi Kia

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

A'lām-Al-Hoda Street, Shahid Shiroodi Street, Arak,
Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Fax

+98 86 3313 3147

Email

karimikia93@gmail.com

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

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period 2 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use documentation by citing the source

From where data/document is obtainable

Mansoreh Karimi Kia Arak University of Medical Sciences
Phone 09181600717 Email karimikia93@gmail.com

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

After receiving the request by phone or email, the data will be sent within 2 weeks.

Comments