Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of perianal injection of dexmedetomidine compared to the effect of ketamine on the postoperative pain and vomiting of perianal fistula: a triple-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of perianal injection of dexmedetomidine compared to the effect of ketamine on pain and vomiting after perianal fistula surgery

Design

A clinical trial of three parallel groups with a control group, triple blinded, randomized, phase 3 on 153 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients are assigned to three groups using randomization with Excel software. All patients are anesthetized in the same way. At the end of the operation, one group is injected with 1.5 µg/kg diluted dexmedetomidine, and the second group is injected with 0.5 mg/kg diluted ketamine around the fistula site. In the third group, medicine is not injected. The study is triple-blind, the researcher, the patient, and the evaluator will not know the type of drug. This study will be conducted in the central operating room of Ghaem Hospital in Mashhad.

Participants/Inclusion and exclusion criteria

This study was conducted on patients aged 18-70 years with American Society of Anesthesiologists(ASA) class I and II and candidates for perianal surgery (perianal fistula) who consented to participate in the study and did not have underlying diseases such as diabetes, high blood pressure, lung or heart problems.

Intervention groups

At the end of the operation, one group was injected with 1.5 micrograms/kg of dexmedetomidine diluted with 4 cc of distilled water by the surgeon around the fistula site locally (subcutaneously) and in the second group of ketamine 0.5 mg/kg diluted with 4 cc of distilled water. It is injected locally in the perianal area (under the skin) and in the third group no medicine is injected.

Main outcome variables

Pain intensity, time required for the first analgesic dose and total analgesic dose Patient vomiting Vital signs include Blood pressure, Heart rate and shivering after the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230912059416N1**
Registration date: **2023-11-11, 1402/08/20**
Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**
Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Seyed Farshid reza Mirsayah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-12-05, 1403/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of perianal injection of dexmedetomidine compared to the effect of ketamine on the postoperative pain and vomiting of perianal fistula: a triple-blind randomized clinical trial

Public title

the effect of perianal injection of dexmedetomidine compared to the effect of ketamine on the postoperative pain and vomiting of perianal fistula

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 70 years Candidate for pre-anal surgery (pre-anal fistula) American Society of Anaesthesiology (ASA) class II and I Informed consent

Exclusion criteria:

Advanced diabetes leads to neuropathy Neuromuscular diseases Psychological and neurological diseases Drug addiction Taking any analgesic or nonsteroidal anti-inflammatory drug(NSAID) in the last 24 hours Pregnancy Body Mass Index(BMI) greater than 30 Preoperative HR less than 60 2nd and 3rd degree atrioventricular (AV) block Taking antihypertensive drugs including Methyldopa, Clonidine and other Alpha2 Adrenergic Agonists Abnormal liver function tests Lung problems High blood pressure Alcoholism Taking N-Methyl-D-Aspartate (NMDA) Antagonists/Memantin History of seizures, high Intraocular pressure (IOP) or Intracranial pressure (ICP) History of sensitivity to ketamine or dexmedetomidine drugs in previous surgeries Chronic pain

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The type of randomization is done using Excel software. The codes assigned to three groups will be written in the form of A, B, and C on separate sheets respectively. Each sheet is folded and glued. which cannot be seen inside. (Allocation concealment). After obtaining the patient's informed consent, a sheet will be removed with the entry of each qualified patient, and according to the code written in it, people will be placed in the three categories of dexmedetomidine or ketamine or the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients do not know the type of drug injected due to being unconscious, and because the drug is injected in the operating room, the researcher and evaluator will not know the type of drug injected.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghaem Hospital, Ahmedabad Street

City

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Razavi Khorasan

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99199-91766

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.MUMS.IRH.REC.1402.111

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified General symptoms and signs Pain, not elsewhere classified Acute pain

Primary outcomes

1

Description

intensity of pain

Timepoint

After the operation in hours 1, 3, 6, 12, and 24

Method of measurement

The Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Time required for the first dose of analgesic
Timepoint
After the operation in hours 1, 3, 6, 12 and 24
Method of measurement
The time interval between the first injection of analgesic with the patient's operation

2

Description
Total analgesic dose received
Timepoint
24 hours after the operation
Method of measurement
Total analgesic doses received during the last 24 hours

3

Description
Patient vomiting
Timepoint
After the operation in hours 1, 3, 6, 12 and 24
Method of measurement
The frequency of vomiting after the operation

Intervention groups

1

Description
Control group: No medicine is injected subcutaneously in the perianal area after surgery.
Category
Treatment - Drugs

2

Description
Intervention group: In this group of patients, 1.5 micrograms/kg of dexmedetomidine diluted with a volume of 4 cc of distilled water is injected locally (subcutaneously) around the fistula by the surgeon.
Category
Treatment - Drugs

3

Description
Intervention group: In this group of patients, 0.5 mg/kg of ketamine diluted with 4 cc of distilled water is injected locally in the perianal area (subcutaneously).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
FarshidReza Mirsayyah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Seyed Farshid reza Mirsayah

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available