# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Jul 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**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**
Mashhad University of Medical Sciences
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mohsen tafaghodi
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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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## 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