

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Investigation of the effect of local Dexmedetomidine on postoperative pain in perianal surgeries

Protocol summary

Study aim

Investigation of the effect of local Dexmedetomidine on postoperative pain in perianal surgeries

Design

Clinical trial with control and parallel groups, randomized and double blind

Settings and conduct

This study will be conducted on 50 candidates for perianal surgery (fissures and hemorrhoids) in Ghaem Hospital. All patients receive 0.5 mg of oral alprazolam for premedication the night before surgery and two hours before surgery. Patients are randomly divided into two groups: After surgery, one group is injected with 1.5 µg / kg local dexmedetomidine in the perianal area and the second group receives no injection. Outcomes such as pain intensity, nausea, vomiting, and vital signs including blood pressure and heart rate are assessed after the surgery. In this study, participants and researcher are unaware of the type of grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Class I and II ASA candidate for perianal surgery (fissures and hemorrhoids) Exclusion criteria: advanced diabetes which leads to neuropathy; neuromuscular diseases; psychological and neurological diseases; drug addiction; use of analgesics or NSAIDs within the last 24 hours ; pregnancy; Body Mass Index is more than 23; preoperative hearth rate is less than 45; second or third-degree AV block; use of antihypertensive drugs including methyldopa, clonidine and other alpha 2 adrenergic agonists

Intervention groups

Intervention group: At the end of the surgery, patients in this group are injected with 1.5 µg/kg diluted dexmedetomidine with a volume of 10 cc in the perianal area. Control group: Control group: In this group, patients do not receive medication.

Main outcome variables

Pain intensity, nausea, vomiting, vital signs including blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100920004780N11**

Registration date: **2021-01-16, 1399/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-16, 1399/10/27**

Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

Mohammad Alipour

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2612

Email address

alipourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-29, 1399/06/08

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of local Dexmedetomidine on postoperative pain in perianal surgeries

Public title

Effect of local Dexmedetomidine on postoperative pain in perianal surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Class I and II ASA candidate for perianal surgery (fissures and hemorrhoids)

Exclusion criteria:

Advanced diabetes which leads to neuropathy
Neuromuscular diseases
Psychological and neurological diseases
Drug addiction
Use of analgesics or NSAIDs within the last 24 hours
Pregnancy
Body Mass Index is more than 23
Preoperative heart rate is less than 45
Second or third-degree AV block
Use of antihypertensive drugs including methyl dopa, clonidine and other alpha 2 adrenergic agonists

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This double-blind clinical trial has a control group and an intervention group in which only the intervention group receives medication. Upon entering the study, an envelope is assigned to each patient, which puts them either in the control or intervention group. The patient and the researcher are unaware of the contents of each envelope.

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.355

Health conditions studied

1

Description of health condition studied

Disease of anus

ICD-10 code

K62.9

ICD-10 code description

Disease of anus and rectum, unspecified

Primary outcomes

1

Description

Pain intensity

Timepoint

1,3,6,12 and 24 hours after operation

Method of measurement

Using Visual Analogue Scale and verbal assessment on a scale of 1 to 10

2

Description

Nausea

Timepoint

1,3,6,12 and 24 hours after operation

Method of measurement

Clinical observations

3

Description

Vomiting

Timepoint

1,3,6,12 and 24 hours after operation

Method of measurement

Clinical observations

4

Description

Vital signs including blood pressure and heart rate

Timepoint

Up to 24 hours after surgery

Method of measurement

Patient monitoring devices

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At the end of the surgery, patients in this group are injected with 1.5 µg/kg diluted dexmedetomidine with a volume of 10 cc in the perianal area.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients do not receive medication.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr. Mohammad Alipour

Street address

Ghaem Hospital, Ahmadabad Avenue

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9176999311

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

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

Dr. Mohammad Alipour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Alipour

Position

Associate professor

Latest degree

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Person responsible for updating data

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Full name of responsible person

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Position

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Fax**Email**

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Web page address

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 data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

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

Carrying out analysis on data is permitted.

Comments