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 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

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
Mashhahd

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
City
Mashhad
Province
Razavi Khorasan
Postal code
9176999311
Phone
+98 51 3840 0000
Email
alipourm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3841 2081
Email
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
Street address
Ghaem hospital, Ahmad Abad blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9176999311
Phone
+98 51 3840 0000
Fax
Email
alipourm@mums.ac.ir

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
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Ghaem hospital, Ahmad Abad blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9176999311

Phone
+98 51 3840 0000

Fax

Email
alipourm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohammad Alipour

Position
Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Ghaem hospital, Ahmad Abad blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9176999311

Phone
+98 51 3840 0000

Fax

Email
alipourm@mums.ac.ir

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