

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effects of administration of intrathecal dexmedetomidine and fentanyl and magnesium sulfate as adjuvant to ropivacaine in duration and onset of sensory and motor block in lower abdominal surgery

Protocol summary

Study aim

Comparison of the effects of administration of intrathecal dexmedetomidine and fentanyl and magnesium sulfate as adjuvant to ropivacaine in duration and onset of sensory and motor block in lower abdominal surgery

Design

This study is clinical trial and double blind. 90 patients candidate lower abdominal surgery in Valiasr hospital will enter this study. We will divide patients in 3 groups by simple randomization. Groups are parallel.

Settings and conduct

90 patients candidate lower abdominal surgery in Valiasr hospital will enter this study. This study is double blind. Outcome assessor and analyzer not aware from grouping. Codes of group are available to analyzer and outcome assessor. We record blood pressure, heart rate, oxygen saturation, pain and duration motor and sensory block in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 60 years, patients candidate lower abdominal surgery, no history of taking beta-blockers and alpha-2 calcium channel blockers and blockers, lack of body mass index greater than 30, lack of cardiovascular problems, no pregnancy, non-localized infection in the spinal cord, no history of allergy to Dexmedetomidine and Ropivacaine and Fentanyl and Magnesium sulfate, lack of arrhythmia, mental and psychological problems. Exclusion criteria: Failure to perform spinal anesthesia, dissatisfaction

Intervention groups

First group: We will inject 3 milliliter (15 milligram) Ropivacaine plus 10 micro gram Dexmedetomidine (1 milliliter) Intrathecal. Second group: We will inject 3 milliliter (15 milligram) Ropivacaine plus 50 micro gram Fentanyl (1 milliliter) Intrathecal. Third group: We will inject 3 milliliter (15 milligram) Ropivacaine plus 1

milliliter Magnesium sulfate 20 % (200 milligram) Intrathecal.

Main outcome variables

blood pressure- heart rate - oxygen saturation- pain - duration motor and sensory block - narcotic drug consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N118**

Registration date: **2019-07-27, 1398/05/05**

Registration timing: **retrospective**

Last update: **2019-07-27, 1398/05/05**

Update count: **0**

Registration date

2019-07-27, 1398/05/05

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of administration of intrathecal dexmedetomidine and fentanyl and magnesium sulfate as adjuvant to ropivacaine in duration and onset of sensory and motor block in lower abdominal surgery

Public title

Comparison of the effects of administration of intrathecal dexmedetomidine and fentanyl and magnesium sulfate as adjuvant to ropivacaine in duration and onset of sensory and motor block in lower abdominal surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 60 years Patients candidate lower abdominal surgery Lack of body mass index less than 30

Exclusion criteria:

Failure to perform spinal anesthesia Dissatisfaction History of taking beta-blockers and alpha-2 calcium channel blockers and blockers Cardiovascular problems Arrhythmia Mental and psychological problems Peripheral and central neuropathy

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B and C. In this method, we selected a number of cards or letters as an intervention group1 and the same number of cards for intervention group 2 and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer and participants are blind (double blind).Outcome assessor and analyzer and participants don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B and C are available to analyzer and outcome assessor.

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

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.ARAKMU.REC.1397.354

Health conditions studied**1****Description of health condition studied**

lower abdominal surgery

ICD-10 code

Y61.0

ICD-10 code description

During surgical operation

Primary outcomes**1****Description**

Mean arterial blood pressure

Timepoint

Every 15 minutes during surgery and recovery time

Method of measurement

Digital sphygmomanometer

2

Description

Heart rate

Timepoint

Every 15 minutes during surgery and recovery time

Method of measurement

ECG

3

Description

Percent of oxygen saturation

Timepoint

Every 15 minutes during surgery and recovery time

Method of measurement

Pulse oximetry

4

Description

Duration of motor block

Timepoint

Every 5 minute

Method of measurement

chronometer

5

Description

Duration of sensory block

Timepoint

Every 1 minute

Method of measurement

chronometer

6

Description

Pain

Timepoint

Recovery and 1, 2, 4, 6,12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale Questionnaire

7

Description

Mean of narcotic

Timepoint

24 hour after surgery

Method of measurement

Observation amount of opiate consumed

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We will inject 3 milliliter (15

milligram) Rupivacaine plus 10 micro gram

Dexmedetomidine (1 milliliter) Intrathecal.

Category

Treatment - Drugs

2

Description

Intervention group: We will inject 3 milliliter (15 milligram) Rupivacaine plus 50 micro gram Fentanyl (1 milliliter) Intrathecal.

Category

Treatment - Drugs

3

Description

Intervention group: We will inject 3 milliliter (15 milligram) Rupivacaine plus 1 milliliter Magnesium sulfate 20 %(200 milligram) Intrathecal.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Valiasr hospital, Valiasr squire

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3848176941

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+98 86 3222 2003

Email

modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam complex, Basij square, Sardasht, Arak

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arjmandzadegan@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

Dr Afsaneh Noruzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Negar Hafalsehe

Position

Medicine student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Modir Valiasr Hospital, Valiasr squire, Shahid Shirodi
street 3814957558

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

Contact With Dr Modir at the following email address.
modir.he@gmail.com

Comments