Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Dexmeditomidine and Rupivacaine 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) Rupivacaine plus 10 micro gram Dexmedetomidine (1 milliliter) Intrathecal. Second group: We will inject 3 milliliter (15 milligram) Rupivacaine plus 50 micro gram Fentanyl (1 milliliter) Intrathecal. Third group: We will inject 3 milliliter (15 milligram) Rupivacaine 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
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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
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target 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 comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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 squre
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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Person responsible for updating data

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Medicine student

Latest degree
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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 squre, 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