Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of adding Neostigmine to Ropivacaine and sufentanilto Ropivacaine in spinal anesthesia for herniorrhaphy surgery

Protocol summary

Study aim

Comparison of the effect of adding Neostigmine to Ropivacaine and sufentanilto Ropivacaine in spinal anesthesia for herniorrhaphy surgery

Design

This study is clinical trial and double blind.105 patients candidate herniorrhaphy surgery in Valiasr hospital will inter this study.We will divide patients in 3 groups by simple randomization.Groups are parallel.

Settings and conduct

105 patients candidate herniorrhaphy surgery in valiasr hospital.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 inguinal hernia surgery, lack of cardiovascular problems, absence of coagulation disorders ,lack of peripheral and central neuropathy, no history of allergy to Neostigmine and Ropivacaine and Sufentanil, non-localized infection in the spinal cord Exclusion criteria:Patient dissatisfaction ,failure to perform spinal anesthesia

Intervention groups

First group: We inject 3 milliliter of Ropivacaine(15 milligram) plus 50 micro gram Neostigmine (Caspian.Co.Rasht)(1 milliliter) in form of intrathecal. Second group: We inject 3 milliliter of Ropivacaine(15 milligram) plus 5 micro gram Sufentanil (Aboreihan.Co)(1 milliliter) in form of intrathecal. Third group: We inject 3 milliliter of Ropivacaine(15 milligram) plus 1 milliliter distilled water (Daropakhsh.Co)(1 milliliter) in form of intrathecal.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N107**
Registration date: **2019-04-23, 1398/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-23, 1398/02/03**
Update count: **0**

Registration date

2019-04-23, 1398/02/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of adding Neostigmine to Ropivacaine and sufentanilto Ropivacaine in spinal anesthesia for herniorrhaphy surgery

Public title
Comparison of the effect of adding Neostigmine to Ropivacaine and sufentanilto Ropivacaine in spinal anesthesia for herniorrhaphy surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
18 to 60 years Patients candidate inguinal hernia surgery Lack of cardiovascular problems Absence of coagulation disorders Lack of peripheral and central neuropathy No history of allergy to Neostigmine and Ropivacaine and Sufentanil Non-localized infection in the spinal cord
Exclusion criteria:
Patient dissatisfaction Failure to perform spinal anesthesia

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

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with random number table in division of groups in two groups A and B and C Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed.Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment:Numbered drug containers

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome assessor and analyzer 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
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
2019-02-24, 1397/12/05

Ethics committee reference number
IR.ARAKMU.REC.1397.356

Health conditions studied

1

Description of health condition studied
Spinal anesthesia

ICD-10 code
X64

ICD-10 code description
Intentional self-poisoning by and exposure to other and unspecified drugs, medicaments and biological substances

Primary outcomes

1

Description
Mean arterial blood pressure

Timepoint
Every 15 minutes during surgery and recovery time and up to 2 hours after surgery

Method of measurement
Barometer

2

Description
Heart rate

Timepoint
Every 15 minutes during surgery and recovery time and up to 2 hours after surgery

Method of measurement
Count

3

Description
Percent of oxygen saturation
Timepoint
Every 15 minutes during surgery and recovery time and up to 2 hours after surgery
Method of measurement
Pulse oximetry

4

Description
Duration of motor block
Timepoint
Every 5 minute
Method of measurement
Minute

5

Description
Duration of Sensory block
Timepoint
Every 1minute
Method of measurement
Minute

6

Description
Pain
Timepoint
Recovery and 2, 4, 8, 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
Milligram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We inject 3 milliliter of Ropivacaine(15 milligram) plus 50 micro gram Neostigmine (Caspian.Co.Rasht)(1 milliliter) in form of intrathecal.
Category
Treatment - Drugs

2

Description
Intervention group: We inject 3 milliliter of Ropivacaine(15 milligram) plus 5 micro gram Sufentanil (Aboreihan.Co)(1 milliliter) in form of intrathecal.
Category
Treatment - Drugs

3

Description
Control group: We inject 3 milliliter of Ropivacaine(15 milligram) plus 1 milliliter distilled water (Daropakhsh.Co)(1 milliliter) in form of intrathecal.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr Hesamedin Modir
Street address
Valiasr hospital, Valiasr squre
City
Arak
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3848176941
Phone
+98 86 3222 2003
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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 Alireza Kamali

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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Person responsible for scientific inquiries

Contact

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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Anahita Fathi

Position
Medicine student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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3848176941

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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

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

They have to write letters to the professors and the university

Comments