# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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**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
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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
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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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**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
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Anesthesiology
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## Person responsible for scientific inquiries

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**Position**
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## Person responsible for updating data

**Contact**
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Arak University of Medical Sciences
**Full name of responsible person**
Anahita Fathi
**Position**
Medicine student
**Latest degree**
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**Other areas of specialty/work**
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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**