

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of relative frequency of post-operative urinary retention in two methods of spinal analgesia with and without opioid.

Protocol summary

Study aim

Comparison of relative frequency of post-operative urinary retention in two methods of spinal analgesia with and without opioid

Design

This study is a Single-blind randomized clinical trial in which the number of patients is determined according to the sample size formula and using a simple randomization method, which uses a random number table for each patient. The code is given and patients are randomly assigned to two treatment groups, with random code selection.

Settings and conduct

To perform spinal anesthesia in both groups, the patient is sitting or lying on his side. We explain the procedure to the patient and ask the patient to work with the anesthesia nurse by taking the knees and giving the abdomen inwards and sticking the chin to the chest. By observing these points by the patient, the injection site is better observed and identified. The skin is then sterilized with a gas and betadine and sterilized with white alcohol. The specialist then inserts the spinal needle into the designated space and injects the drug into that area. However, before injecting the drug, it is first pulled out of the liquid to ensure the correct location of the needle. The study will be conducted at Firoozgar and Rasoul Akram Hospitals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients are candidates for lower limb orthopedic surgery Patients are candidates for anorectal surgery Exclusion criteria: Patients with a history of urinary problems, Patients with a history of diabetes, Pregnant women

Intervention groups

First group: Patients candidates for lower limb Orthopedic surgery or Anorectal surgery under spinal anesthesia with Opioid. Second group: Patients candidates for lower limb Orthopedic surgery or Anorectal surgery under spinal anesthesia without

Opioid.

Main outcome variables

Urinary retention, complaining of incomplete urination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200525047563N1**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Azadeh Emami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2237 0673

Email address

azademami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of relative frequency of post-operative urinary retention in two methods of spinal analgesia with and without opioid.

Public title
Comparison of relative frequency of post-operative urinary retention in two methods of spinal analgesia with and without opioid.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients are candidates for lower limb orthopedic surgery
 Patients are candidates for anorectal surgery
Exclusion criteria:
 Patients with a history of urinary problems Patients with a history of diabetes Pregnant women

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, a simple randomization method is used, which is done using a table of random numbers. To use the number of random numbers, we first determine the reading path of the table numbers (for example, top, bottom, left or right). Then we assume certain numbers for each group (for example, even numbers for intervention A and odd numbers for intervention B). Then we touch on one of the numbers and move in one of the predetermined directions and record the numbers and assign them to different groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, a person who is responsible for analyzing statistical data is not aware of the treatment process and study groups and the information is provided to that person in groups A and B. This helps the person's personal opinion not to affect the results

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.IUMS.FMD.REC.1399.136

Health conditions studied

1

Description of health condition studied

Lower limb Orthopedic surgery

ICD-10 code

Y79.3

ICD-10 code description

Surgical instruments, materials and orthopedic devices (including sutures) associated with adverse incidents

Primary outcomes

1

Description

Urinary retention

Timepoint

after surgery

Method of measurement

Ask the patient

Secondary outcomes

1

Description

Complaints of incomplete urination

Timepoint

After surgery

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group: To perform spinal anesthesia in the first group, first fluid therapy with normal saline injection serum up to 300 cc is performed. Then the patient is placed sitting or lying on his side. We explain the procedure to the patient and ask the patient to work with the anesthesia nurse by taking the knees and giving the abdomen inwards and sticking the chin to the chest. By observing these points by the patient, the injection site is better observed and identified. The skin is then sterilized with a gas and betadine and sterilized with white alcohol. Then, the specialist doctor inserts a spinal needle of the appropriate size in the designated space and injects 1.5-2 cc of marcaine (0.05%, produced by Cobel Darou) in addition to 25 micrograms of fentanyl. However, before injecting the drug, it is first pulled out of the liquid to ensure the correct location of the needle.

Category

Treatment - Drugs

2

Description

To perform spinal anesthesia in the second group, first fluid therapy with normal saline injection serum up to 300 cc is performed. Then the patient is sitting or lying on his side. We explain the procedure to the patient and ask the patient to work with the anesthesia nurse by taking the knees and giving the abdomen inwards and sticking the chin to the chest. By observing these points by the patient, the injection site is better observed and identified. The skin is then sterilized with a gas and betadine and sterilized with white alcohol. Then the specialist doctor enters the spinal needle with the appropriate size in the prescribed space and injects 2.5-2 cc of marcaine (0.05% produced by Cobel Darou) in that place. However, before injecting the drug, it is first pulled out of the liquid a little to ensure the correct entry of the needle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Azadeh Emami

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Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motavalian

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azadeh Emami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available