Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of spinal anesthesia with combination of 0.5% hyperbaric bupivacaine 1 mg (0.2 mL)+fentanyl 20 µg (0.4 mL)+5% dextrose solution 1.4 mL (total 2 mL)on postoperative pain in transurethral resection of prostate surgery

Protocol summary

Summary

This study design to evaluate the characteristics of selective spinal anesthesia using 0.5% hyperbaric bupivacaine 1 mg (0.2 mL)+fentanyl 20 µg (0.4 mL)+5% dextrose solution 1.4 mL (total 2 mL) in compare with hyperbaric bupivacaine 10 mg in elderly patients undergoing transurethral resection of prostate. The triple blind randomized clinical trial study will be conduct on 72 patients aged 50 to 85 years scheduled for prostatic endoscopic surgery under spinal anesthesia in Imam Reza and Razi hospitals of Birjand University of Medical Sciences. The patients will be allocated in two groups according to the type of drugs used for intrathecal injection. The Fentanyl group will receive 0.5% hyperbaric bupivacaine 0.2 mL+fentanyl 20 µg+5% dextrose 1.4 mL, and the bupivacaine group will receive 0.5% hyperbaric bupivacaine 2 ml intrathecally. Mean arterial pressure (MAP), heart rate (HR) will be measured every 5 minutes until the end of surgery and results compare at each time point between groups. The maximum motor response will be compared between two groups after achieving to the desired sensory level for TURP. Postoperative pain immediately and at 15, 30 minutes and at 2, 6, 12, 24 hours after surgery will be evaluated and compared between two groups. Also, complications such as nausea, vomiting, changes in blood pressure, and heart are compared in both groups during and after the operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081221383N8**
Registration date: **2017-10-17, 1396/07/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2017-05-23, 1396/03/02

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of spinal anesthesia with combination of 0.5% hyperbaric bupivacaine 1 mg (0.2 mL)+fentanyl 20 µg (0.4 mL)+5% dextrose solution 1.4 mL (total 2 mL)on postoperative pain in transurethral resection of prostate surgery

Public title
Using of combination of bupivacaine 1 mg and fentanyle 20 mg for spinal anesthesia in transurethral resection of prostate surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: All the patients aged 50 to 85 years old with american society of anesthesia physical classificaton system (ASA) 1 or 2 who were scheduled for prostatic endoscopic surgery under spinal anesthesia.
Exclusion criteria: Patients with histories of back surgery, infection in the back, coagulopathy, hypersensitivity to local anesthetics or opioids, mental disturbance, or neurological disease were excluded.
Age
From **50 years** old to **85 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Birjand university of medical sciences
Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand, Iran.
City
Birjand
Postal code
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
Ir.bums.REC.1396.46

Health conditions studied

1

Description of health condition studied
Intrathecal injection in transuretheral resection of prostat surgeries
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
postoperative pain
Timepoint
15, 30 minutes and 2, 6, 12, 24 hours after surgery
Method of measurement
visual analog scale (VAS)

2

Description
The doses of meperidine
Timepoint
Within 24 hours
Method of measurement
Based on the total dose of injections in 24 hours (questionnaire)

Secondary outcomes

1

Description
Motor block
Timepoint
When the peak sensory and cold blocks were obtained at dermatom of T10
Method of measurement
modified Bromage scale

2

Description
Nausea
Timepoint
During the surgery and immediately, 15 and 30 minutes, 2, 6, 12, 24 hours after surgery.
Method of measurement
Visual analog scale (VAS)

3

Description
Vomiting
Timepoint
During the surgery to 24 hours after surgery
Method of measurement
vomiting or not during surgery and upto 24 hours thereafter

4

Description
Mean arterial pressure
Timepoint
each 5 minute to the end of the surgery
Method of measurement
mmhg with oscillometric barometer

5

Description
heart rate
Timepoint
each 5 minutes to the end of the surgery
Method of measurement
beat per minutes with digital ECG monitor.

Intervention groups

1

Description
Intrathecal injection of 0.5% Hyperbaric bupivacaine 1mg (0.2 cc) + 5% Dextrose (1.4 cc)+ Fentanyl 20 µg (0.4 cc)
Category
Prevention

2

Description
Administration of hyperbaric bupivacaine 10 mg intrathecally
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital of Birjand university of medical sciences
Full name of responsible person
Dr.Amir Sabertanha
Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor of research of Birjand university of medical sciences
Full name of responsible person
Dr.Tooba Kazemi
Street address
vice chancellor of research, Birjand University of Medical Sciences, Ghafari Street, Birjand, Iran
City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
vice chancellor of research of Birjand university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty