

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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

Name

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Name of organization / entity

Birjand University of Medical Sciences

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Iran (Islamic Republic of)

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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 fentanyl 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 classification 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 committee 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

lr.bums.REC.1396.46

Health conditions studied

1

Description of health condition studied

Intrathecal injection in transurethral resection of prostatic 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 dermatome 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

Full name of responsible person

Dr. Amir Sabertanha

Position

Assistant professor of anesthesia

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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