

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of low dose bupivacaine and fentanyl in spinal anesthesia on the level of sensory and motor block in elderly patients

Protocol summary

2017-06-02, 1396/03/12

Summary

80 patients aged between 65-5 years candidates for trans urethral prostatectomy with ASA class I and II would be allocated one of two study groups. One group will take 7.5 mg bupivacaine 0.5% and 25 µgr fentanyl while another group would take only 10 mg of bupivacaine 0.5%. Blood Pressure, pulse rate and O2 saturation would be monitored during surgery. Then spinal anesthesia with 25 gauge needle in lumbar L3-L4 or L4-L5 would be done. Then anesthesia leveling would be taken during 5th, 10th and 30th minutes using a sterile needle. The time of anesthesia by adding the time of sensory recovery to two levels lower than the most upper primary level would be documented. Motor block also would be documented at 10th, 20th and 30th minutes using Bromidge score. If the patient complains pain during operation (VAS=4-6) 25 µgr fentanyl and if VAS>7 general anesthesia would be induced. Systolic Blood pressure, pulse rate would be documented before and after anesthesia induction during surgery. SBP<90 mmhg would be managed with ephedrine, while if decreased blood pressure is accompanying with heart rate lower than 60 beats, atropine would be administered. Itching, nausea, vomiting and respiratory depression during and after operation would be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702226148N4**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Hakimeh Alreza Amiri

Name of organization / entity

Babol University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Babol research deputy of university of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low dose bupivacaine and fentanyl in spinal anesthesia on the level of sensory and motor block in elderly patients

Public title

The effect of bupivacaine and fentanyl level of sensory and motor in elderly patients

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: age 65 to 85 candidates for

prostatectomy Exclusion criteria: patients with a history of bleeding disorders, neurological diseases, loss of consciousness, presence of infection at the injection site

Age

From **65 years** old to **85 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Babol University of Medical Science

Street address

Rohani Hospital, Ganjafrooz Street

City

Babol

Postal code

4717641367

Approval date

2015-10-26, 1394/08/04

Ethics committee reference number

MUBABOL.REC.1394.178

Health conditions studied

1

Description of health condition studied

Sensory-Motor Block

ICD-10 code

R00-R99

ICD-10 code description

Symptoms and signs involving the nervous and musculoskeletal systems

Primary outcomes

1

Description

Level of sensory block

Timepoint

Minutes:10 ,20 after spinal anesthesia

Method of measurement

Sensory level was assessed using the tip of a needle sterilized and with alcohol cotton.

Secondary outcomes

1

Description

Motor block

Timepoint

Minutes: 10,20,30 and in the end of surgery and 2hours after spinal anesthesia

Method of measurement

Motor block was assessed and recorded using Bromage Scale(BS=0 full knee and foot flexion, BS=1 ability to move knee, BS=2 ability to move feet only, BS=3 full motor block)

2

Description

Patient s blood pressure

Timepoint

Blood pressure was monitored and recorded every 3 minutes for the first 10 minutes following spinal anesthesia and then every 5 minutes until completion of surgery.

Method of measurement

Noninvasive blood pressure cuff

3

Description

Patient s heart rate

Timepoint

Heart rate was monitored and recorded every 3 minutes for the first 10 minutes following spinal anesthesia and then every 5 minutes until completion of surgery.

Method of measurement

Monitoring of ECG and Pulse oximetry

4

Description

Pain

Timepoint

Minutes: 10,20,30 during surgery.

Method of measurement

VAS (Visual Analogues Scale)

5

Description

Nausea and vomiting

Timepoint

During surgery.

Method of measurement

Question & observation

6**Description**

Respiratory depression

Timepoint

After spinal anesthesia

Method of measurement

Examination& observation

Intervention groups**1****Description**

In intervention group, standard regimen including bupivacaine 0.5 % (7.5 gr Astra Zeneca, Sweden) and Fentanyl (25 µgr, Rotexmedic, Germany) was prescribed.

Category

Treatment - Drugs

2**Description**

In control group, standard regimen including bupivacaine 0.5 % (7.5 gr Astra Zeneca, Sweden)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rohani Hospital

Full name of responsible person

Hakimeh Alereza Amiri

Street address

Ganjafrooz Street

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Babol Univercity of Medical Science

Full name of responsible person

Dr Ali Bigani

Street address

Babol Univercity of Medical Science, Ganjafrooz Street

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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

Vice Chancellor for Research, Babol Univercity of Medical Science

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**

Babol University of Medical Science

Full name of responsible person

Dr Maedeh Jafarzadeh

Position

Residents of Anesthesiology

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Babol University Of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Full name of responsible person
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Position
Anesthesiologist

Other areas of specialty/work

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Phone

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