Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of prostatic regional block on post-operative urethral catheter discomfort in transurethral prostatectomy surgery

Protocol summary

Study aim
The effect of prostatic regional block on post-operative urethral catheter discomfort in transurethral prostatectomy surgery

Design
Randomized double-blind randomized clinical trial with trial phase 2-3

Settings and conduct
Intervention group: Patients in the first group will received 0.5 mg / kg bupivacaine during one minute for periprostatic block by transrectal method at the end of the surgery. Control group: Patients will not received with 0.5 mg / kg bupivacaine during one minute for periprostatic block by transrectal method at the end of the surgery. The surgeon and the person preparing the medicine and providing it to the surgeon were aware of the type of study; While the patient, the patient evaluator in the recovery room and the statistical analyst were unaware of the type of study and block performed.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:50-70 years, ASA one and two, patients undergoing prostate surgery, patients under general anesthesia. Exclusion Criteria: Uncontrolled underlying disease, history of chronic pelvic pain, opium addicts, anxiety disorders, restlessness, time and space loss, confusion, tremor, chills, seizures, tinnitus, bradycardia, decreased cardiac function, hypotension, Cardiovascular collapse, respiratory arrest, nausea and vomiting, cases in which the surgeon decides to perform open prostatectomy for any reason, including active bleeding, history of discopathy, history of coagulopathy.

Intervention groups
Intervention group: Patients in the first group will received 0.5 mg / kg bupivacaine during one minute for periprostatic block by transrectal method at the end of the surgery. Control group: Patients will not received with 0.5 mg / kg bupivacaine during one minute for periprostatic block by transrectal method at the end of the surgery.

Main outcome variables
Pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20141009019470N108**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **prospective**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

Registration date
2021-02-06, 1399/11/18

Registrant information
Name
Farzaneh Masihi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-20, 1399/12/02
Expected recruitment end date
2021-03-24, 1400/01/04
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of prostatic regional block on post-operative urethral catheter discomfort in transurethral prostatectomy surgery

Public title
The effect of prostatic regional block on post-operative urethral catheter discomfort in transurethral prostatectomy surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
50-70 years ASA one and two patients undergoing prostate surgery patients under general anesthesia

Exclusion criteria:
Uncontrolled underlying disease History of chronic pelvic pain Opium addicts Anxiety disorders Restlessness Time and space loss Confusion Tremor Shivering Seizures, tinnitus Bradycardia Decreased cardiac function Hypotension Cardiovascular collapse Respiratory arrest Nausea and vomiting Cases in which the surgeon decides to perform open prostatectomy for any reason, including active bleeding History of discopathy History of coagulopathy

Age
From **50 years** old to **70 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a random table taken from sealedenvelped.com and 4 and 6 permutation blocks patients are divided into two groups .Patients were placed in the intervention or control group upon entering the operating room.

Blinding (investigator's opinion)
Double blinded

Blinding description
The surgeon and the person preparing the medicine and providing it to the surgeon were aware of the type of study; While the patient, the patient evaluator in the recovery room and the statistical analyst were unaware of the type of study and block performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Province
Fars

Postal code
7134844119

Approval date
2016-06-17, 1395/03/28

Ethics committee reference number
IR .SUMS.MED.REC.1395.71

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia

ICD-10 code
D29.1

ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
post-operative urethral catheter discomfort

Timepoint
At the beginning of the recovery and then 30, 60, 90 and 120 minutes later and at the time of transfer to the ward

Method of measurement
During the two hours of patients' stay in recovery, the amount of pain and discomfort caused by the urethral catheter is divided into three degrees: Zero: Do not feel discomfort caused by the catheter. One: Patients feel mild discomfort after the question but do not complain on their own. Two: Patients without question express a feeling of urination, discomfort in the suprapubic or burning urination. Three: Feeling uncomfortable with unquestioning behaviors such as kicking the bed, yelling at the nurse, trying to remove the urethral catheter.

2

Description

Morphine consumption in recovery

Timepoint

Time of discharge from recovery

Method of measurement

observation

Secondary outcomes

1

Description

Blood pressure

Timepoint

During the operation and after the operation until the transfer to the recovery and in recovery every 15 minutes.

Method of measurement

Monitoring

2

Description

Recovery Stay

Timepoint

Duration of presence in recovery

Method of measurement

When Aldrete score time reaches 6

Intervention groups

1

Description

Intervention group: Patients in the first group will received with 0.5 mg / kg bupivacaine during one minute for periprostatic block by transrectal method at the end of the surgery.

Category

Prevention

2

Description

Control group: Patients will not received with 0.5 mg / kg bupivacaine during one minute for periprostatic block by transrectal method at the end of the surgery.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Fatane Jamshidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatane Jamshidi

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Its against our policies.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available