

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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 receive 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 receive 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 receive 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 receive 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

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 sealedenveloped.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

Street address

Namazi Hospital, Namazi Square

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

fatanejamshidi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

vcrd@sums.ac.ir

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

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

fatanejamshidi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ali Karami

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

alk1380@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.com

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