Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

To investigate the effectiveness of ultrasound-guided pre-emptive superior hypogastric plexus block (SHPB)on the severity of catheter-related bladder discomfort (CRBD) in patients undergoing transurethral resection of theprostate (TURP) at Shohada Ashayer Hospital in Khorramabad.

Protocol summary

Study aim

To evaluate the effectiveness of ultrasound-guided prophylactic Superior Hypogastric Plexus Block (SHPB) on the severity of Catheter-Related Bladder Discomfort (CRBD) in patients undergoing Transurethral Resection of the Prostate (TURP).

Design

A randomized, double-blind (patient, surgeon, and outcome assessor), sham-controlled clinical trial with parallel allocation.

Settings and conduct

Conducted at Shohadaye Ashayer Hospital, Khorramabad. Patients first receive spinal anesthesia (0.5% bupivacaine at L3-L4 or L4-L5). Immediately after, the anesthesiologist performs the intervention (actual or sham block), while the patient and the rest of the medical team remain blinded.

Participants/Inclusion and exclusion criteria

Inclusion CriteriaMale patients aged 45 to 80 years, candidates for elective TURP surgery under spinal anesthesia, with American Society of Anesthesiologists (ASA) physical status I or II and Exclusion Criteria History of prostate/bladder surgery, urethral stricture, bladder cancer, bladder capacity < 150 cc, chronic use of antimuscarinics or analgesics, coagulopathy, injection site infection, or conversion from spinal to general anesthesia.

Intervention groups

Following spinal anesthesia, patients in this group receive an ultrasound-guided Superior Hypogastric Plexus Block (SHPB) using the in-plane technique at the L5-S1 level, with an injection of 10 ml of 0.25% bupivacaine.

Main outcome variables

The severity of Catheter-Related Bladder Discomfort (CRBD), assessed using a 4-point scale (none, mild, moderate, severe) at 0, 1, 2, 6, 12, and 24 hours post-operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230410057871N11**
Registration date: **2026-06-10, 1405/03/20**
Registration timing: **prospective**

Last update: **2026-06-10, 1405/03/20**
Update count: **0**

Registration date

2026-06-10, 1405/03/20

Registrant information

Name

Arian Karimi Rouzbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3324 1229

Email address

arian.karimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-21, 1405/03/31

Expected recruitment end date
2026-08-22, 1405/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To investigate the effectiveness of ultrasound-guided pre-emptive superior hypogastric plexus block (SHPB)on the severity of catheter-related bladder discomfort (CRBD) in patients undergoing transurethral resection of theprostate (TURP) at Shohada Ashayer Hospital in Khorramabad.

Public title
The effect of hypogastric nerve plexus block on bladder discomfort after prostate surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men aged 45 to 80 years old candidates for elective transurethral resection of the prostate (TURP) under spinal anesthesia, with ASA physical status I or II
Exclusion criteria:
Age
From **45 years** old to **80 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization (using Allocation Random Software) with a block size of 4 and an allocation ratio of 1:1. Allocation concealment is performed using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE).
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blind. The patient is blinded to the intervention type as it is performed after spinal anesthesia. The urologist and the clinical outcome assessor are also blinded to the group assignments. Only the anesthesiologist performing the block is aware of the allocation.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences
Street address
Moallem Street, Shahid Anushiravan Rezaei Square
City
Khoamabad
Province
Lorestan
Postal code
6813833946
Approval date
2026-03-01, 1404/12/10
Ethics committee reference number
IR.LUMS.REC.1404.368

Health conditions studied

1

Description of health condition studied
Catheter-Related Bladder Discomfort (CRBD) following Transurethral Resection of the Prostate (TURP)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of Catheter-Related Bladder Discomfort (CRBD)
Timepoint
0 (recovery entry), 1, 2, 6, 12, and 24 hours after surgery.
Method of measurement
Standard 4-point scale

Secondary outcomes

1

Description
Rescue analgesic consumption
Timepoint
In the first 24 hours post-surgery
Method of measurement
Amount of pethidine 25 mg IV or diclofenac suppository

2

Description
Time to first analgesic request

Timepoint
Post-operative period
Method of measurement
Recording the interval until the first rescue need.

3

Description
Adverse events (nausea, vomiting, hematoma at injection site)
Timepoint
Post-operative period
Method of measurement
Clinical observation and reporting.

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Ashayer Hospital
Full name of responsible person
Arian Karimi Rouzbahani
Street address
Enghelab street
City
Khorramabad
Province
Lorestan
Postal code
6816933133
Phone
+98 66 3323 6401
Email
shohadahospital@lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Peyman Astaraki
Street address
Khorramabad, Kamalvand, Km 4
Khorramabad–Borujerd Road, Pardis Academic Complex, Lorestan University of Medical Sciences, Deputy of Research and Technology
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 0333 1660
Email
peymanastaraki@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Arian Karimi Rouzbahani
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Khorramabad, Kamalvand, Km 4
Khorramabad–Borujerd Road, Pardis Academic Complex, Lorestan University of Medical Sciences, Deputy of Research and Technology
City
Khorramabad
Province
Lorestan
Postal code
6814993165
Phone
+98 930 675 7977
Email
arian.karimi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Siavash Beiranvand

Position
Medical doctor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
5th kilometer of Khorramabad–Borujerd Road, opposite to Kahrizak village, Lorestan University of Medical Sciences Complex, Khorramabad , Lorestan,Iran

City
Khorramabad

Province
Lorestan

Postal code
6814993165

Phone
+98 930 675 7977

Email
beiranvandsiavash@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Arian Karimi Rouzbahani

Position
Medical doctor

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
5th kilometer of Khorramabad–Borujerd Road, opposite to Kahrizak village, Lorestan University of Medical Sciences Complex, Khorramabad , Lorestan,Iran

City
Khorramabad

Province
Lorestan

Postal code
6814993165

Phone
+98 930 675 7977

Email
arian.karimi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available