

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

U-shape incision on on prostate capsule: New intrapritineal laparoscopic technique in simple prostatectomy.

Protocol summary

Study aim

U-shape incision on on prostate capsule: New intrapritineal laparoscopic technique in simple prostatectomy

Design

A clinical trial with two groups of patients: parallel, therapeutic, blanced block randomization, single blind (patient). 10 patients referred to Sinai Hospital.

Settings and conduct

10 patients at Sina Hospital. blanced block randomization, single blind(patient). Patients are divided into two groups: Group 1: intrapritineal laparoscopic technique and U-shape incision on prostate capsule. Group 2: Extraperitoneal laparoscopic technique and direct incision on the prostate capsule.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients with indications for prostate surgery: including infection, bladder stones, refractory retention, non-response to medical treatment, and refractory hematuria, Consent to participate in the study. Exclusion criteria:Abnormal rectal examination,Active infection,Severe heart or lung disease.

Intervention groups

Intervention group 1:intrapritineal laparoscopic technique and U-shape incision on prostate capsule. Intervention group 2:Extraperitoneal laparoscopic technique and direct incision on the prostate capsule.

Main outcome variables

Duration of surgery, Average bleeding during surgery, Average length of hospital stay.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N15**

Registration date: **2021-07-28, 1400/05/06**

Registration timing: **prospective**

Last update: **2021-07-28, 1400/05/06**

Update count: **0**

Registration date

2021-07-28, 1400/05/06

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6634 8560

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mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-30, 1400/06/08

Expected recruitment end date

2022-01-28, 1400/11/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

U-shape incision on on prostate capsule: New intrapritineal laparoscopic technique in simple prostatectomy.

Public title

intrapritineal laparoscopic technique

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with indications for prostate surgery infection bladder stones refractory retention non-response to medical treatment refractory hematuria Consent to participate in the study

Exclusion criteria:
Abnormal rectal examination Active infection Severe heart or lung disease

Age
From **18 years** old to **70 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a single-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team. Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician. The patient is placed in (intrapritineal laparoscopic technique and U-shape incision on prostate capsule) or (Extraperitoneal laparoscopic technique and direct incision on the prostate capsule) group based on the randomly selected envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients who have given their consent to participate in the study will be treated with intrapritineal laparoscopic technique and U-shape incision on prostate capsule or Extraperitoneal laparoscopic technique and direct incision on the prostate capsule. The patient has no information about the surgical procedure and the design.

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sina Hospital Research Ethics Committee

Street address

Sina Hospital - Hassan Abad St. - Tehran - Iran

City

تهران

Province

Tehran

Postal code

1136746911

Approval date

2020-06-28, 1399/04/08

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1399.008

Health conditions studied

1

Description of health condition studied

Intraperitoneal laparoscopic prostatectomy

ICD-10 code

N42

ICD-10 code description

Other and unspecified disorders of prostate

Primary outcomes

1

Description

Improving surgical technique

Timepoint

before and one month after surgery

Method of measurement

International prostatectomy score, maximum urinary flow rate and Prostate-Specific Antigen

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intrapritineal laparoscopic technique and U-shape incision on prostate capsule. During surgery; the patient is placed in the supine and intubated via a NG Tube. A Foley catheter 22f is inserted and the patient 's legs is placed at a 30-degree angle. Then a two-centimeter incision is made below the umbilicus, after that the peritoneum is opened and a 10 mm port is placed. The abdomen is then slowly filled with CO2 gas and two ports (5mm) are inserted in the umbilicus and the lateral of rectum under direct vision. In the next step,

peritoneum is opened in the anterior part of the bladder and then the fourth port is placed in the suprapubic area for suctioning. The prostate capsule is opened transversely by a U-Shape incision at the distance of 0.5 cm from the bladder neck. At this time, the prostate adenoma is removed by suction and after inserting a 22f catheter, the capsule is sutured continuously. Patient is discharged with the catheter. One week later, the patient catheter is removed and 3 months later, IPSS and QMAX will measured again.

Category

Treatment - Surgery

2**Description**

Intervention group: Extraperitoneal laparoscopic technique and direct incision on the prostate capsule

Category

Treatment - Surgery

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

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

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Urology Research Center, Sina Hospital, Imam Khomeini St., Tehran, Iran.

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

Tehran 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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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Dr Akram Mirzaei

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

demographic information anonymously

When the data will become available and for how long

one year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Any analysis can be done with the consent of the main researcher

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir
00982166348560

What processes are involved for a request to access data/document

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

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