

Can prostate biopsies be safely done without antibiotics? A study on infection risks after a common procedure in the Philippines

Submission date 04/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/06/2025	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/08/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Antibiotic resistance is a growing global health problem. It happens when bacteria and other germs become resistant to the medicines used to treat infections. This can lead to longer illnesses, more serious health problems, and fewer treatment options.

Prostate cancer is the most common cancer in men worldwide. To diagnose it, doctors often need to take a small sample of the prostate, called a biopsy. Traditionally, this is done through the rectum, which carries a risk of infection—even when antibiotics are used.

A newer method, called a transperineal biopsy, goes through the skin between the anus and scrotum instead of the rectum. This method is cleaner and may not need antibiotics at all. This study aims to find out if it's safe to skip antibiotics when using this newer method, which could help reduce unnecessary antibiotic use and fight resistance.

Who can participate?

Men aged 40 to 75 who are scheduled for a transperineal prostate biopsy may be eligible. Participants must be generally healthy, have no signs of infection, and meet other medical criteria.

What does the study involve?

Participants will be randomly assigned to one of two groups: one will receive antibiotics before the biopsy, and the other will not. All participants will be monitored for 30 days after the procedure to check for any infections or other complications.

What are the possible benefits and risks of participating?

There are no direct health benefits for participants. However, those who do not receive antibiotics may avoid side effects from these drugs.

The main risk is infection, which is already a known risk of prostate biopsy. Studies suggest that the risk is low and not increased by skipping antibiotics in this type of biopsy.

Where is the study run from?
St. Luke's Medical Center (Philippines).

When is the study starting and how long is it expected to run for?
January 2024 to July 2025.

Who is funding the study?
St. Luke's Medical Center (Philippines).

Who is the main contact?
Dr Joseph Vincent M. Songco, jvmsongco@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Post procedural infections in antibiotic prophylaxis-free transperineal prostate biopsy: a double blinded randomized controlled clinical trial, a 2 center experience in the Philippines

Study objectives

Omitting prophylactic antibiotics is non inferior to giving prophylactic antibiotics in terms of infection rate in transperineal prostate biopsies

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 05/06/2024, St. Luke's Medical Center Institutional Ethics Review Committee (279 E. Rodriguez Sr. Ave., Quezon City, 1112, Philippines; +63 28-723-0101 ext. 7391; ethicsreview@stlukes.com.ph), ref: SL-23295

Study design

2 center interventional double blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Safety

Health condition(s) or problem(s) studied

Urinary tract infection

Interventions

Participants were assigned in a 1:1 ratio to either no prophylaxis (GroupA) or prophylaxis with 1g intravenous cefoxitin (GroupB). Randomization was based on a pre-generated sequential list from random.org and maintained by a research assistant not involved in patient care or outcome assessment. Allocation remained concealed from both the primary investigator and the participants.

In Group A, no prophylactic antibiotics will be given, For GroupB, a single 1g dose of Intravenous Cefoxitin will be administered 1 hour prior to the procedure. All subjects underwent general laryngeal mask anesthesia. Upon induction, Excess hair in the perineal area was clipped. The perineum was prepped with 10% povidone iodine (Betadine), applied in accordance with institutional protocol. MRI/ultrasound fusion-guided prostate biopsy was performed using the Koelis system. Both targeted and systematic cores were obtained in all participants under sterile conditions. Final Histopathology results will be collected.

Patients will be followed for 30 days post procedure. An initial assessment is done at 7 days using a symptom checklist for signs and symptoms of infection. Patients will also be asked to have a urine culture submitted. After the initial assessment, patient's who present with signs of infection will undergo further assessment, including clinical evaluation, and will be treated accordingly. Type of infection and treatment will be documented..

Lower urinary tract symptoms (e.g., dysuria, frequency, hematuria) that were transient, mild, and self-limiting were not classified as postoperative infections. Decisions to treat were guided by symptom severity and the presence of fever. Decision to admit patient for hospitalization will depend on the assessment of the primary investigator along with the attending Urologist. Patients who developed symptoms were followed until full resolution.

Patients who do not present with signs of infection will be followed for 30 days and will be asked to report symptoms of such. All infection occurring beyond 7 days, emergency room consults, hospital admissions, and non-infectious complications will be recorded.

Intervention Type

Other

Primary outcome(s)

Incidence of Urinary Tract Infection or Sepsis within 30 days post biopsy. This will be measured through a symptom check list including symptoms of Fever, hematuria, dysuria, suprapubic pain, perineal pain, or foul smelling urine, with bacteria identified on urine culture. Sepsis is defined using the Sepsis 2 definition of confirmed infection through urine culture accompanied by at least two of the following: A body temperature above 38°C (100.4°F) or below 36°C (96.8°F), A heart rate greater than 90 beats per minute, A respiratory rate greater than 20 breaths per minute, or a PaCO₂ less than 32 mmHg, A white blood cell count greater than 12,000 cells/μL, less than 4,000 cells/μL, or more than 10% immature (band) forms.

Key secondary outcome(s)

1. 30 day readmission rates measured using patient records
2. Overall 30 day complication rates measured by Clavien-Dindo scoring

Completion date

01/07/2025

Eligibility

Key inclusion criteria

1. Age 40-75 years
2. American Society of Anesthesiologists score of I or II
3. Those undergoing Transperineal Prostate Biopsy
4. Urine Culture Negative Patients
5. Non Tender Prostate on DRE
6. Asymptomatic Patients
7. Charlson Score <5

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Upper age limit

75 years

Sex

Male

Total final enrolment

140

Key exclusion criteria

1. Acute prostatitis within the last 6 months.
2. History of documented Urinary Tract Infection (UTI), or symptoms of UTI (painful micturition, Frequency, Urgence, suprapubic or flank pain, cloudy and foul-smelling urine) for the past 6 months.
3. Tender and boggy prostate on initial DRE
4. With ongoing antibiotics treatment for the past month
5. History of antibiotic allergy
6. Prior definitive therapy for prostate cancer, such as radiation therapy or partial gland ablation.
7. Those with uncontrolled diabetes mellitus, immunocompromised or immunosuppressed status.
8. Those with other pre-existing urinary tract conditions such as Benign Prostatic Hyperplasia in retention, Urinary retention from neurogenic causes, and those with indwelling stents or urethral catheters
9. Those with Prosthetic Heart Valves
10. Patients with ongoing infection elsewhere
11. Patients with Bleeding Disorders
12. Patients with Asymptomatic Bacteriuria

Date of first enrolment

04/06/2024

Date of final enrolment

01/07/2025

Locations**Countries of recruitment**

Philippines

Study participating centre

St. Luke's Medical Center

279 E. Rodriguez Sr. Ave.

Quezon City

Philippines

1112

Study participating centre

St. Luke's Medical Center Global City

Rizal Drive cor. 32nd St. 5th Ave

Taguig City

Sponsor information

Organisation
St. Luke's Medical Center

ROR
<https://ror.org/02h4kdd20>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Luke's Medical Center

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	Participant information sheet		28/08/2025	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	version 6	07/01/2025	28/08/2025	No	No
Statistical Analysis Plan	version 2.0	15/01/2025	28/08/2025	No	No