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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

Registration date
28/06/2025

Overall study status
Completed

Last Edited
25/06/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
1. 30 day readmission rates measured using patient records
2. Overall 30 day complication rates measured by Clavien Dino scoring

Overall study start date
05/01/2024

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

Age group
Adult

Lower age limit
40 Years

Upper age limit
75 Years

Sex
Male

Target number of participants
136

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
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.stluke.com.ph/

ROR
https://ror.org/02h4kdd20

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Luke's Medical Center

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
01/09/2025

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