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Investigating blood and urine bacteria in patients with uncertain PSA (prostate-specific antigen) levels

Submission date
14/12/2024

Recruitment status
No longer recruiting

Registration date
17/12/2024

Overall study status
Completed

Last Edited
16/12/2024

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
This study aims to explore how bacteria in urine can help detect prostate cancer (PCa) early. By using advanced techniques to analyze urine samples, researchers hope to improve the accuracy of diagnosing patients with uncertain PSA levels, which can aid in better clinical decisions and treatments.

Who can participate?
Patients with elevated PSA levels (greater than 4 ng/ml) who are being treated at the Department of Urology, Jiangnan University Medical Center, can participate in this study.

What does the study involve?
Participants will provide urine samples for analysis. The study will use various advanced techniques to examine these samples, including 5R16S sequencing, non-targeted metabolomics analysis, and OLINK proteomics analysis. Participants will receive free medical tests as part of the study.

What are the possible benefits and risks of participating?
There are no risks involved in participating in this study. Participants will benefit from free medical tests, which can provide valuable health information.

Where is the study run from?
The study is conducted at Jiangnan University Medical Center in China.

When is the study starting and how long is it expected to run for?
The study is expected to start in November 2023 and run until December 2025.

Who is funding the study?
The study is funded by the National Natural Science Foundation of China.

Who is the main contact?
Professor Ninghan Feng, n.feng@njmu.edu.cn

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ChiCTR2400093612

Study information

Scientific Title
Study on serum and urine microbiota in patients with PSA in the gray zone

Study objectives
Based on the urine microecology, we seek new biomarkers and construct new diagnostic models to assist in the clinical diagnosis of patients in the PSA range of 4 to 10 ng/ml, reduce the number of patients undergoing unnecessary invasive tests, and reduce the waste of medical resources.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/12/2023, the Ethics Committee of Jiangnan University Medical Center (No.68 Zhongshan Road, Liangxi District, Wuxi City, Jiangsu Province, Wuxi, 214000, China; +86 139 2112 8288; 9862022074@jiangnan.edu.cn), ref: Y-168

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied
Patients with an outpatient diagnosis of elevated PSA

Interventions
1. Sample collection and processing
This study is approved by the Ethics Committee of Jiangnan University Medical Center (2023-Y-168). We will collect patients with elevated PSA in the Urology Department of Jiangnan University Medical Center from November 2023 to December 2025. The following exclusion criteria are considered: 1. Patients whose PSA value is outside the range of 4-10ng/ml will be excluded after re-examination after admission; 2. Exclude patients who have used antibiotics in

the past 3 months; 3. Exclude patients with urinary tract infection; 4. Exclude other tumor patients; 5. Patients who dropped out of the study will be excluded.

Specific sample collection and treatment methods: After standardized disinfection of the urethral opening, midstream urine samples will be collected in the morning, and blood samples will be collected before treatment. All samples will be processed within 1 hour. The blood samples will be centrifuged at 4000rpm at 4 for 10min, 1ml of serum will be taken from each blood sample and stored in a sterile EP tube at -80. The urine sample will be centrifuged at 4 at 9600rpm for 10min, and the supernatant will be discarded. The precipitation will be re-suspended with 1ml pre-cooled PBS and preserved at -80.

2. Urine microbiota sequencing, serum metabolite sequencing, serum proteomics analysis
We will send the collected urine samples and blood samples to the corresponding sequencing companies for analysis, and after returning the analysis results, we will analyze the results of each group again, and try to conduct a joint analysis based on statistics and the corresponding software and website platform.

3. Statistical analysis
We expect to use statistical analysis techniques such as random forests, logistic regression, and mediation analysis. The feedback results of each group will be analyzed by homologous random forest and logistic regression to find the corresponding markers of a single group of students, and to construct the corresponding diagnostic model of a single group of students. Finally, the three omics will be connected through mediation analysis, and the combined diagnosis model of the three omics will be constructed.

Intervention Type
Other

Primary outcome(s)
PSA is measured in the early morning of the day after admission. Midstream specimen of urine was collected in the morning, while blood samples were collected before treatment. They will be measured using 5r16S, OLINK and Non-target metabolite sequencing.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patients with an outpatient diagnosis of elevated PSA
2. Patients are between 40 and 95 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
95 years

Sex
Male

Key exclusion criteria
1. Patients with retested PSA values outside 4-10ng/ml range after admission were excluded;
2. Patients who had used antibiotics in the past 3 months were excluded;
3. Patients with urinary tract infection were excluded;
4. Patients with other tumors were excluded;
5. Patients who dropped out of the study were excluded.

Date of first enrolment
30/11/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
China

Study participating centre
Jiangnan University Medical Center
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Sponsor information

Organisation
Jiangnan University Medical Center

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ninghan Feng, n.feng@njmu.edu.cn.

IPD sharing plan summary
Available on request