ISRCTN50547972 https://doi.org/10.1186/ISRCTN50547972

A study looking at a urine test combined with ultrasound to detect bladder cancer in people with blood in their urine

Submission date 27/04/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/04/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/04/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Haematuria (blood in the urine) is a common symptom that can be a sign of bladder cancer. Currently, the standard way to diagnose bladder cancer is a procedure called cystoscopy, which involves inserting a camera into the bladder through the urethra. This test is invasive, uncomfortable, and expensive.
The aim of this study is to see whether a new urine test (called UroCAD), either on its own or combined with a simple ultrasound scan of the bladder, can accurately detect bladder cancer in people with haematuria. If successful, this noninvasive approach might help some patients avoid unnecessary cystoscopies.

Who can participate?
Adults (aged 18 years or older) who have recurrent haematuria. This includes people with visible (gross) blood in the urine that comes and goes without pain, after kidney problems have been ruled out, and people with persistent microscopic blood in the urine (found on a urine test) for more than 6 months, after a urinary tract infection has been excluded.

What does the study involve?
Each participant will provide a oneoff morning urine sample (30–50 ml) for UroCAD testing. This test looks for certain DNA changes (chromosomal instability) in cells shed from the bladder lining. Participants will also have a standard bladder ultrasound scan. Finally, they will undergo a cystoscopy with biopsy or surgery to obtain tissue for a definite diagnosis (the reference standard). The study compares the results of the UroCAD test and the ultrasound with the tissue diagnosis to see how accurate the noninvasive tests are.

What are the possible benefits and risks of participating?
There is no direct benefit to participants in this study, but the information gathered will help doctors develop better, less invasive tests for bladder cancer in the future.
Risks are very low. The urine test and ultrasound are painless and have no known health risks.

Cystoscopy and biopsy are standard clinical procedures that carry a small risk of discomfort, bleeding, or urinary infection – these risks are the same for participants as for any patient undergoing these procedures outside the study.

Where is the study run from?
The study is led by the Department of Urology, the Second Affiliated Hospital of Jiaxing University, Jiaxing, China. It also involves several other hospitals in the Jiaxing area (the First People's Hospital of Jiashan and the First People's Hospital of Pinghu).

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

Who is funding the study?
The study is funded by a grant from the Science and Technology Project Plan of Jiaxing (grant number 2024AY10005) (China)

Who is the main contact?
Dr Chenye Tang, john99233@126.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Chenye Tang

ORCID ID
https://orcid.org/0000-0001-8640-197X

Contact details
Department of Urology, The Second Affiliated Hospital of Jiaxing University, 1518 North Huancheng Road
Jiaxing
China
314000
+86 (0)13750781238
john99233@126.com

Additional identifiers

Study information

Scientific Title
Prospective evaluation of UroCAD combined with ultrasonography for detecting bladder urothelial carcinoma in patients with hematuria

Acronym
PECUS

Study objectives
To evaluate the diagnostic performance of urinary exfoliatedcell chromosomal copynumber aberration detection (UroCAD), alone and in combination with bladder ultrasonography, for detecting bladder urothelial carcinoma in patients presenting with hematuria, using histopathological examination as the reference standard.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/12/2023, Medical Ethics Committee of Second Affiliated Hospital of Jiaxing University (1518 North Huancheng Road, Jiaxing, 314000, China; +86 (0)573 82050475; jxeykjk1003@163.com), ref: 2023 ZFYJ 134 01

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Bladder urothelial carcinoma in patients presenting with hematuria

Interventions
This prospective observational diagnostic accuracy study consecutively enrolls adult patients presenting with recurrent hematuria. Participants provide a midstream first morning urine sample (30–50 ml) for UroCAD testing, which uses lowcoverage wholegenome sequencing (LCWGS) to detect chromosomal instability (CIN) and genomewide copynumber variation (CNV) profiles in exfoliated urothelial cells. All participants also undergo bladder ultrasonography, performed by radiologists blinded to the UroCAD results. The reference standard is histopathological examination of bladder tissue obtained via cystoscopy or surgical resection. The diagnostic performance of UroCAD alone, ultrasonography alone, and two prespecified combined rules (“CIN or ultrasound” and “CIN and ultrasound”) is evaluated using sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy, and area under the receiver operating characteristic curve (AUC). Secondary analyses assess the association between CNV burden and tumor stage, as well as the discriminative ability of individual chromosomal arms. No randomisation or intervention allocation is applied.

Intervention Type
Mixed

Primary outcome(s)
1. Diagnostic performance of UroCAD alone and in combination with ultrasonography: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall accuracy, and area under the receiver operating characteristic curve (AUC) measured using histopathological examination of bladder tissue obtained via cystoscopy or surgical resection as the reference standard, at a single timepoint at enrollment (cross-sectional assessment; no follow-up required for primary outcome)

Key secondary outcome(s))

Completion date
04/07/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Recurrent hematuria, including either:
2.1. Intermittent, painless, gross hematuria after renal causes have been ruled out by nephrology consultation; or
2.2. Persistent microscopic hematuria for >6 months confirmed by urinalysis, following exclusion of urinary tract infection
3. Able to provide a midstream first-morning urine sample (30–50 mL) for UroCAD testing
4. Willing and able to undergo cystoscopy and histopathological examination (or surgical resection for pathological confirmation) as the reference standard
5. Provide written informed consent to participate

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
153

Key exclusion criteria
1. Unwillingness to provide a urine sample
2. Refusal to participate or inability to provide informed consent
3. Prior history of other non-urothelial malignancies
4. Incomplete clinical records

Date of first enrolment
14/01/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
The Second Affiliated Hospital of Jiaxing University

Funder(s)

Funder type

Funder Name
Science and Technology Bureau of Jiaxing City

Alternative Name(s)
Jiaxing Science and Technology Bureau, Jiaxing Municipal Scienceand Technology Bureau, Jiaxing City Science and TechnologyBureau,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available