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Bladder EpiCheck - testing a urine test to help detect bladder cancer in people with blood in their urine

Submission date 30/01/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/01/2025	**Overall study status** Ongoing	
Last Edited 16/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Blood in the urine (haematuria) can be a sign of bladder or urothelial cancer. Currently, when someone has blood in their urine, they will often need to have a camera examination of their bladder (cystoscopy) to check for cancer. The main purpose of this study is to test how well a new urine test (called Bladder EpiCheck) can detect urothelial carcinoma including bladder cancer and upper tract urothelial cancer in people who have blood in their urine. We are looking for participants who are due to have a scheduled standard camera examination of their bladder (called a cystoscopy) within 60 days of joining the study. We will ask them for one urine sample. The study will measure how accurately Bladder EpiCheck can identify both people who do have bladder cancer (measured as sensitivity) and people who don't have bladder cancer (measured as specificity), by comparing the urine test results tested with the Bladder EpiCheck to the results from the camera examination and any tissue samples taken. The study will also compare how well Bladder EpiCheck performs against another standard urine test called cytology, and will specifically look at how good it is at detecting more aggressive types of bladder cancer.

Who can participate?
People aged 45 years or older who have had blood in their urine (either visible or detected through testing) within the last 6 months and are scheduled to have a camera examination of their bladder. Participants must not have previously been diagnosed with bladder cancer, had a bladder camera examination for blood in urine in the past 2 years, or been treated for prostate or kidney cancer in the last 12 months.

What does the study involve?
Participants will be asked to provide a urine sample when they attend their scheduled hospital appointment for their bladder camera examination. This sample will be tested at a main central laboratory using Bladder EpiCheck. Neither the participant nor their doctor will be told the results of this test as it is for research purposes only. The study will compare the Bladder EpiCheck results with the results from standard hospital tests.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, but the research may help improve how bladder cancer is detected in the future. There are no known risks from taking part as participants are only being asked to provide a urine sample.

Where is the study run from?
The study is being run at multiple NHS hospitals across the UK

When is the study starting and how long is it expected to run for?
December 2024 to August 2026

Who is funding the study?
Nucleix Ltd

Who is the main contact?
Jennifer Stuart, jennifer@lindushealth.com

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
353608

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DMS No: 68096

Study information

Scientific Title
Bladder EpiCheck® for the primary detection of urothelial carcinoma in subjects presenting with haematuria: a multicentre, prospective, double-blind, non-interventional, single-arm study

Study objectives
The purpose of this study is to further validate the performance of the Bladder EpiCheck test for the detection of primary urothelial carcinoma in subjects presenting with haematuria (non-visible [micro] or visible [macro/gross]) within 6 months of enrollment as compared to standard of care cystoscopic examination and pathological confirmation (if indicated).

The sensitivity and specificity of the test will be compared to the Reference Standard, based on cystoscopy and pathology if indicated.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/02/2025, Ethics North East - Newcastle & North Tyneside 1 (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8384; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 25/NE/0035

Study design
Multicentre prospective double-blind non-interventional single-arm study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied
Urothelial carcinoma

Interventions
Participants will be asked to attend their routine hospital appointment, and at this appointment provide a urine sample. There will be no additional hospital visits required for this research. This urine sample will be sent to a laboratory to be tested using the Bladder EpiCheck. The participant or doctor will not be told of the results. They will be compared to the usual hospital results for research purposes only.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bladder EpiCheck

Primary outcome measure
The sensitivity and specificity of Bladder EpiCheck to detect primary urothelial carcinoma, calculated versus the Reference Standard defined by cystoscopy, imaging, and, if indicated, pathological confirmation) in subjects presenting with haematuria (visible and/or non-visible). Measured at a single timepoint.

Secondary outcome measures
Measured at a single timepoint:
1. Non-inferiority of Bladder EpiCheck overall sensitivity vs cytology in the detection of primary urothelial carcinoma
2. Non-inferiority of Bladder EpiCheck specificity vs cytology in the detection of primary urothelial carcinoma
3. The sensitivity of the Bladder EpiCheck test to detect pathologically confirmed high-grade urothelial carcinoma, including HG non-muscle invasive and muscle-invasive disease

Overall study start date
18/12/2024

Completion date
01/08/2026

Eligibility

Key inclusion criteria

1. Subjects aged 45 years or older
2. Subjects who are willing and able to provide written informed consent and adhere to study procedures
3. Subjects presenting with visible and/or non-visible haematuria within 6 months prior to study enrollment
4. Subjects scheduled to undergo standard-of-care cystoscopy for urinary bladder examination within 60 days after study enrollment
5. Subjects who are able to produce at least 10 ml of voided urine

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Subjects with history of urothelial cancer in the bladder and/or upper urinary tract
2. Subjects who had prior cystoscopy for haematuria within the past 2 years
3. Subjects previously enrolled in this study
4. Subjects treated for prostate cancer within the last 12 months
5. Subjects treated for kidney cancer within the last 12 months
6. Subjects with untreated urinary tract infection
7. Subjects with symptomatic urinary tract stones (e.g. flank pain)
8. Subjects on dialysis for end-stage renal failure
9. Subjects with a long-term urinary catheter
10. Pregnancy (self-reported)
11. Subjects who, because of medical status, or frailty is not expected to be able to complete the full diagnostic pathway

Date of first enrolment
17/06/2025

Date of final enrolment
17/10/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
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Study participating centre
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Study participating centre
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Nucleix Ltd

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date