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A real-world evaluation of a bladder cancer biomarker pathway

Submission date 06/11/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 11/02/2026	**Overall study status** Ongoing	
Last Edited 11/02/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Bladder Cancer (BC) is the seventh most common cancer in Western Society, with around 10,000 new BC cases registered per year in the UK. BC is not immediately life-threatening, but up to 44% of patients with BC progress to a more serious type. This type of BC has a 27-50% 5-year survival rate. Outcomes for BC have not improved for over 25 years; therefore, it is important to research better diagnosis and treatment methods. This study looks at the tests patients have when they are sent to the hospital for possible BC. When a patient has blood in their urine, they go to the hospital where they have their urine tested and have a test called a flexible cystoscopy. A small camera on a flexible tube is used to look inside the bladder. This can be quite uncomfortable and also means the patient has to visit the hospital to have it done. A new testing kit has been made that can check for BC by looking at biomarkers (small molecules) in patients' urine. This study wants to see if it is practical and easy for patients to do a urine sample at home and send it back to the lab for testing. This study is the first step in helping researchers learn if some patients can be checked for BC using this urine test without having a flexible cystoscopy.

Who can participate?
Adult patients referred to the hospital with blood in their urine will be asked if they want to take part.

What does the study involve?
Participants will have all their usual tests and appointments, but also be provided a urine sample from home and post it (free) back to the lab. The urine kit will be sent to the participant's home and will include instructions on when and how to collect the urine sample. The samples will be given unique ID numbers so lab researchers will not know the names of the participants. The research team will also check the patients' notes to see the outcome of the hospital tests.

What are the possible benefits and risks of participating?
Benefits: Participants will not experience any direct benefit from participating in the study. However, this study hopes to provide information to guide a better and less invasive diagnostic pathway for suspected bladder cancer patients in the future.

Risks: This study has minimal participant burden and no significant risks. Participants may face barriers in providing and returning a urine sample due to access to post box or mobility difficulties.

Where is the study run from?
North Bristol NHS Trust (Southmead Hospital), UK

When is the study starting and how long is it expected to run for?
The study is expected to start 01/12/2025 with recruitment starting 01/02/2026 and the study ending 31/06/2027.

Who is funding the study?
1. Nonacus (formerly Informed Genomics), UK
2. NHS Somerset, Wiltshire, Avon and Gloucestershire Cancer Alliance, UK

Who is the main contact?
Prof Jonathan Aning, jonathan.aning@nbt.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
364053

Protocol serial number
R&D:5650

Study information

Scientific Title
Urinary biomarker real world evaluation- bladder cancer pathway

Acronym
ARMADA- BCP

Study objectives
This study aims to find out if GALEAS® Bladder testing kits could improve the real-world pathway for patients referred to hospital with blood in their urine. This study will see if it practical and easy for patients to provide a urine sample at home and send it off for testing. Hopefully, this might highlight if the test could be used to reduce the number of unnecessary cystoscopies undertaken on patients in the future. This study also aims to asses the diagnostic performance of the GALEAS® Bladder testing kits in the real-world. We are also looking at the acceptability of the test in the real world.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/12/2025, East of England - Cambridge South Research Ethics Committee (Equinox House City Link, Nottningham, NG2 4LA, United Kingdom; -; Cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0280

Primary study design
Observational

Study design
Multicentre cohort observational study using sample analysis and questionnaires

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Haematuria/ suspected bladder cancer

Interventions
Urine samples will undergo urinary biomarker analysis. Samples returned to Nonacus Clinical Services will undergo DNA analysis using the following methodology. Sequencing reads generated via Illumina technology are aligned to the human reference genome (hg19) using BWA. Unique Molecular Identifiers (UMIs), extracted from the i7 index reads, are used to annotate each read on a per-original-molecule basis. A proprietary bioinformatics pipeline, based on widely used open-source tools, is then applied. Consensus reads are generated from a minimum of three reads sharing the same UMI and identical genomic start and stop positions. Variant calling is performed using bamreadcount to extract reference and non-reference read depths.
Biomarker analysis results will be classes as either positive, negative or inconclusive. Data will be also be collected about number and quality of samples returned.

Intervention Type
Genetic

Primary outcome(s)
1. Proportion of returned GALEAS® Bladder kits meeting predefined quality thresholds (adequate urine volume, DNA yield ≥25ng, QC passed) measured using an evaluation against a

composite quality standard according to standardised laboratory protocols; urine volume will be measured using a volumetric measuring device; and DNA yield will be measured using Illumina (next generation sequencing) technology at one time point

Key secondary outcome(s)
Patient acceptability of home urine testing (TFA) and of the GALEAS test will be assessed through the following secondary outcome variables measured using study data at one time point, unless stated:
1. Feasibility of postal return system (return rate of GALEAS® Bladder kits)
2. Timeliness of receipt of GALEUS® Bladder result to inform clinical care
3. Sensitivity and specificity of GALEAS® Bladder vs. standard HC diagnostics measured using flexi ± cytology/imaging and, where appropriate, cystoscopy and bladder biopsy
4. Proportion of positive GALEAS® results among patients with ultimately negative HC investigations
5. Modelling of reduction in flexis if GALEAS® Bladder is used as a triage tool
6. Environmental/lifecycle impact modelling of alternate pathways, including those involving reduced procedures
7. Anticipated facilitators and barriers to implementation from health care professional perspectives measured using the Consolidated Framework for Implementation Research (CFIR)] at the end of study recruitment at each participating centre

Completion date
01/10/2027

Eligibility

Key inclusion criteria
1. Patients referred for the investigation of symptoms suspicious of bladder cancer (BC)
2. Minimum age of 18 years
3. Able to provide verbal informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Previous diagnosis of bladder or upper tract urothelial cancer (UTUC) in the last 5 years
2. Previous entry into the study
3. Must not have a long-term catheter or urostomy
4. Limited understanding of English (due to the lack of resources available to have translators in clinics to facilitate informed consent)

Date of first enrolment
01/02/2026

Date of final enrolment
01/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
England
TA1 5DA

Study participating centre
Great Western Hospitals NHS Foundation Trust
Great Western Hospital
Marlborough Road
Swindon
England
SN3 6BB

Study participating centre
GP Care
GP CARE UK LTD
160 AZTEC WEST
BRISTOL
England
BS32 4TU

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Industry

Funder Name
Nonacus (formerly Informed Genomics)

Funder Name
Somerset, Wiltshire, Avon and Gloucestershire Cancer Alliance

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated will be published as a supplement to the results publication.

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