

Bladder cancer detection using a non-invasive urinary biomarker URO17™ in patients with suspected bladder cancer

Submission date 27/05/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/06/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/12/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Bladder cancer is the second most common cancer of the urinary system. The most common symptom of bladder cancer is haematuria, blood in the urine. Patients being investigated for haematuria may undergo radiology scans and an examination of the bladder using a camera which is called cystoscopy. Cystoscopy is an invasive, sometimes painful and expensive procedure. A high proportion of bladder cancers recur after treatment therefore radiology and cystoscopy are routinely repeated. These tests are often carried out alongside non-invasive tests such as Urine Cytology in which urine samples are looked at under microscope to try and identify cancer cells. However urine cytology is not very accurate therefore there is a need for a new non-invasive method of cancer detection.

The URO17™ Bladder Cancer Test has been shown in previous studies to be very effective at detecting bladder cancer cells in urine samples. This study aims to test this in a larger group of patients. This will be done by applying the test to the urine samples of patients who are having standard investigations for haematuria and then comparing the results.

Who can participate?

The study will recruit 500 patients attending the Urology Clinic at the University Hospital of Wales Cardiff for haematuria investigations.

What does the study involve?

The patients will be asked to give consent to provide a urine sample and for their clinical data to be used in the study.

A smaller group of patients will be asked to complete a questionnaire which would aim to find out if patients would accept having a urine sample test instead of a cystoscopy to investigate their bladder.

There will also be a small evaluation project to test the performance of a potential home urine collection system.

What are the possible benefits and risks of participating?

None

Where is the study run from?
University of Cardiff (UK)

When is the study starting and how long is it expected to run for?
January 2021 to May 2026

Who is funding the study?
Accelerate programme (co-funded by the Welsh European Funding Office, European Regional Development Fund and Welsh Government's Health and Social Services Group) (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

298341

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

SPON 1846-21

Study information

Scientific Title

Urinary Biomarker URO17 Study

Study objectives

To assess the ability of a urinary biomarker, URO17 to discriminate between bladder cancer and non-bladder cancer in patients presenting with haematuria

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/06/2021, London - Queen Square Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), ref: 21/PR/0745

Study design

Single centre prospective observational study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Bladder cancer

Interventions

Patients newly presenting with haematuria will have urine samples collected. These samples will be used for URO17 and cytology tests. They will also have standard investigations including cystoscopy. Details of their diagnosis will be recorded.

There will also be a small evaluation project in approximately 100 patients to investigate the performance of an upstream home urine collection system to evaluate performance and compatibility with the URO17 test. A subset of patients (250 patients) will be asked to complete a questionnaire prior to, and following flexible cystoscopy, to determine the acceptability of urinary biomarkers as a replacement for flexible cystoscopy.

Intervention Type

Other

Primary outcome(s)

Bladder cancer diagnosis measured by Urinary Biomarker URO17 at baseline and review of patient notes following completion of investigations (within 60 days)

Key secondary outcome(s)

1. Patient acceptability measured using VAS questionnaire at baseline and following cystoscopy procedure within 1 hour
2. Home collection kit accuracy measured by repeat URO17 urinary biomarker test at baseline
3. Cost effectiveness measured by costing of procedures during clinic appointment and review of the literature
4. Bladder cancer diagnosis measured by Urine Cytology and review of patient notes at baseline and review of patient notes following completion of investigations (within 60 days)

Completion date

01/05/2026

Eligibility**Key inclusion criteria**

1. Participant is willing and able to give informed consent
2. Attending Rapid Access Haematuria Clinic (RAHC) for further investigation for suspected bladder cancer
3. Patients aged >18 years with either visible haematuria or with symptomatic LUTS associated with non-visible haematuria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

500

Key exclusion criteria

1. Participant unable to give informed consent
2. Previous history of urinary tract malignancy
3. Previous history of pelvic radiotherapy
4. Active urine infection
5. Be currently taking investigational drugs or actively participating in a treatment trial for any condition
6. Be an employee of the study site or the sponsor
7. Have a medical condition or serious intercurrent illness, or other circumstance that, in the Investigator's judgment, could jeopardize the candidate's safety as a study subject, or that could interfere with study objectives

Date of first enrolment

07/07/2021

Date of final enrolment

12/10/2022

Locations

Countries of recruitment

United Kingdom

Study participating centre**University Hospital of Wales Cardiff**

Cardiff and Vale University Health Board

Heath Park

Cardiff NO COUNTRY SPECIFIED, assuming England

England

CF14 4 XW

Sponsor information

Organisation

Cardiff University

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Government

Funder Name

Accelerate programme (co-funded by the Welsh European Funding Office, European Regional Development Fund and Welsh Government's Health and Social Services Group).

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet		14/04/2021	18/06/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes