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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	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 18/06/2021	**Overall study status** Completed	
Last Edited 10/06/2025	**Condition category** Cancer	

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 November 2023

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

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298341

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 298341, 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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

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

Secondary outcome measures
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)

Overall study start date
04/01/2021

Completion date
30/11/2023

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

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
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CF14 4 XW

Sponsor information

Organisation
Cardiff University

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Sponsor type
University/education

Website
https://www.cardiff.ac.uk/

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

Publication and dissemination plan
Publication and dissemination plan
Once the experiment and the data analysis is completed, the results will be submitted for publication in peer-reviewed journals to disseminate the findings more widely subject to a review of confidential information. The results may also contribute to scientific posters and presentations at conferences. The aim will be to effectively communicate the information to clinicians working in this area to get engagement with the novel technology. Communication of the results to relevant patient groups may also be appropriate.

Use of the information in this way will only be done with consultation with all participating collaborators on the project.

Where appropriate and with the permission of key collaborators, external dissemination could also include press releases, journal articles, conference presentations, reports, news items on websites etc.

Intention to publish date

01/05/2026

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?
Participant information sheet		14/04/2021	18/06/2021	No	Yes
HRA research summary			26/07/2023	No	No