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A study to assess how well a new urine test can identify bladder cancer in patients with blood in their pee

Submission date 04/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/11/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 21/01/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Seeing blood in the urine (visible haematuria), or having blood detected in a urine sample by your GP (non-visible haematuria), is common. However, haematuria is also a symptom that is associated with bladder cancer and so needs to be investigated further by referral to hospital. About 10% of patients referred to haematuria clinic will be diagnosed with bladder cancer – but for most patients, no reason is identified, or patients are diagnosed with benign conditions such as urine infections or kidney stones.

As part of the investigations that take place in hospital, patients undergo flexible cystoscopy (flexi)- a narrow flexible camera is passed through the water pipe into the bladder to see any abnormalities that might be in the bladder. However, flexi is an invasive procedure which can be uncomfortable and is not perfect - a flexi inspection of the bladder will miss bladder cancer in around 1 in 7 to 1 in 10 patients. When we look at results from the UK and worldwide for all patients referred to haematuria clinics, we see that over 80% of patients do not have any abnormalities diagnosed. Therefore, many patients undergo flexi when they may not need to. However, at present, it is impossible to know who these patients are before the investigations are carried out.

Researchers have been working to identify new ways to diagnose bladder cancer instead of flexi. Urine tests are showing the most promise for this as when a patient has bladder cancer, some of the cancer cells are shed from the lining of the bladder into the urine and the abnormalities in these cells can be detected.

Study aims:

With funding from Cancer Research UK, researchers at the University of Birmingham have developed a urine test which may be as good as flexi. In this study, we would like to find out how accurate this new urine test is. If we can show that the test is as good as (or even better than) flexi when used in haematuria clinic, then it could be used in the future to identify which patients may have bladder cancer and need to have a flexi, and which patients are very unlikely to have bladder cancer and do not need a flexi.

Who can participate?
Patients who have experienced blood in their urine, and other symptoms suspicious for bladder cancer, and have been referred by the GP to hospital for further investigations.

What does the study involve?
Participants who agree to take part in the study will sign an informed consent and will be asked to answer a short survey about themselves. They will be given a urine sample collection kit and asked to complete a urine sample at home, which they will post to the research lab in the packaging provided. Participants will be contacted by the research team one and two years after the initial visit.

What are the possible benefits and risks of participating?
The purpose of this study is to evaluate how well the new test can detect bladder cancer in patients who experience blood in the urine, to see if it could be used in the future as a tool to help decide which patients should have a flexi and which patients do not need a flexi. This study could help to change the haematuria clinic pathway and reduce the number of patients having a flexi who don't really need one. Although there is no direct benefit to patients in taking part, we hope that the information obtained from this study may result in changes to the way patients with suspected bladder cancer are diagnosed in the future.
There are no risks to your health in taking part in the study. The only disadvantage would be giving up your time to collect the urine sample at home 7-10 days after having a flexi.

Where is the study run from?
University of Birmingham (UK)
King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2021 to April 2028

Who is funding the study?
Cancer Research UK (Early Detection and Diagnosis Committee)

Who is the main contact?
Anna Haire, anna.haire@kcl.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
322811

Central Portfolio Management System (CPMS)
57525

Protocol serial number
EDDPJT-Nov21\100017

Study information

Scientific Title
BC-Recon: Diagnosing Bladder Cancer - evaluating the role of a urinary biomarker test in the Reconfiguration of the haematuria clinic investigations

Acronym
BC-Recon

Study objectives
A DNA-based diagnostic urine test for bladder cancer (BC) could reduce by >45% the number of patients requiring flexible cystoscopy for the investigation of haematuria.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/07/2023, London - Dulwich Research Ethics Committee (Health Research Authority, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8286; dulwich.rec@hra.nhs.uk), ref: 23/PR/0732

Primary study design
Observational

Study design
Observational; Design type: Case-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bladder cancer

Interventions
In this proposed study (called 'BC-Recon'), we will run the GALEAS® Bladder test alongside the usual 'standard' care in haematuria clinics. We plan to recruit 3200 patients from 6 large urology units over a 3-year period; we will request a single one-off urine sample from participants, to be donated for study purposes, as well as request the opportunity to contact them again 1 and 2 years later to find out if they were diagnosed with cancer at a later date than the haematuria clinic. Patients diagnosed with BC in haematuria clinics will have the standard haematuria clinic tests, as well as the GALEAS® Bladder test. A further 400 haematuria clinic patients without a BC diagnosis will also undergo testing with GALEAS® Bladder. We will then compare the GALEAS® Bladder test findings to the standard tests. This will enable us to calculate how well GALEAS® Bladder can identify which patients have BC (and need a flexi), and which patients are very unlikely to have BC (and so don't need flexi). These statistical calculations will lead to measurements of:
• the proportion of patients with BC diagnosed by flexi who were also diagnosed by GALEAS® Bladder ('sensitivity')
• the proportion of patients without BC who were correctly identified by a negative GALEAS® Bladder test ('specificity')
• how accurate GALEAS® Bladder is when combined with the other haematuria clinic investigations apart from flexi (urinalysis + urine cytology + imaging + Birmingham urine test);
• the proportion of flexis that could be avoided using GALEAS® Bladder in the haematuria clinic setting.

If these calculations and measurements are promising, then these findings could lead to a large clinical trial where some patients have the GALEAS® Bladder test when they are referred to haematuria clinic by their GP. We think that using GALEAS® Bladder in haematuria clinic could reduce the number of patients requiring flexible cystoscopy by at least 45%. This would result in 30,000-60,000 fewer haematuria clinic flexis each year.

Intervention Type
Other

Primary outcome(s)
1. Sensitivity of the GALEAS® Bladder test for Bladder Cancer will be calculated from the proportion of the patients who receive a diagnosis of bladder cancer following the haematuria clinic investigations, who test positive with GALEAS® Bladder.
2. Specificity of the GALEAS® Bladder test for Bladder Cancer will be calculated from the proportion of the patients who don’t receive a diagnosis bladder cancer following the haematuria clinic investigations, who test positive with GALEAS® Bladder.

Key secondary outcome(s)
There are no secondary outcome measures.

Completion date
01/04/2028

Eligibility

Key inclusion criteria
1. Patients attending a haematuria clinic (one or two stop appointment in a urology clinic in secondary care) for experiencing haematuria and/or for the investigation of symptoms suspicious of bladder cancer (BC)
2. Minimum age of 18 years
3. Provision of written informed consent

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
4615

Key exclusion criteria
1. Previous diagnosis of bladder or upper tract urothelial cancer (UTUC) within the last 5 years
2. Previous entry into the study
3. Limited understanding of English (due to the lack of resource available to have translators in HCs to facilitate informed consent or provide the at-home urine sample collection kits with translated instructions)

Date of first enrolment
01/10/2023

Date of final enrolment
17/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
Ashford & St Peters Hospital
Guildford Road
Chertsey
England
KT16 0PZ

Study participating centre
Northern Care Alliance, Salford
Salford Royal Hospital
Mayo Building
Stott Ln
Salford
England
M6 8HD

Study participating centre
Northern Care Alliance, Oldham
Royal Oldham Hospital
Rochdale Rd
Oldham
England
OL1 2JH

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Huddersfield Royal Infirmary

Acre St
Lindley
Huddersfield
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HD3 3EA

Study participating centre
East Lancashire Hospitals NHS Trust
Casterton Avenue
Burnley
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BB10 2PQ

Study participating centre
Medway NHS Foundation Trust
Windmill Rd
Gillingham
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ME7 5NY

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Church Lane
Exeter
England
EX2 5DW

Study participating centre
Surrey and Sussex Healthcare NHS Trust
Canada Ave
Redhill
England
RH1 5RH

Study participating centre
Princess Royal Hospital
Lewes Road
Haywards Heath
England
RH16 4EX

Study participating centre
St Richard's Hospital
Spitalfield Lane
Chichester
England
PO19 6SE

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The Bladder Cancer Research Centre (BCRC, University of Birmingham) and King's College London (KCL) all support the wider dissemination of information from the research that they conduct, and increased cooperation between investigators. Clinical trial/study data are collected, managed, analysed, stored, shared and archived according to Standard Operating Procedures and Quality Management Systems in order to ensure the enduring quality, integrity and utility of data.
Trial/study results are published in peer-reviewed journals, and open access policies adhered to. Formal requests for data sharing are considered in line with the individual policies of BCRC and KCL with due regard given to funder, sponsor and relevant guidelines. Requests should be received via a standard proforma describing the nature of the proposed research and extent of data requirements. Requests will be reviewed by the Study Management Group in terms of scientific merit and ethical considerations, including patient consent. Data sharing is undertaken if proposed projects have a sound scientific rationale or patient benefit, as agreed by the Study Management Group.
Data are not normally shared until primary study results have been published so as not to compromise the principal research question(s). Data recipients are required to sign a data release form which describes the conditions for release and requirements for data transfer, storage,archiving, publication and Intellectual Property.

IPD sharing plan summary

Available on request