

Urinary Xpert bladder cancer detection test in patients with haematuria

Submission date 03/11/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/01/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In Europe, more than 120,000 people are diagnosed with bladder cancer each year. Early diagnosis is very important to improve the success of treatment for bladder cancers. However, many patients do not have symptoms at early stages, which makes this challenging. One symptom which may be an early sign of bladder cancer is the presence of blood in the urine. 1 in 5 adults with blood in the urine are found to have bladder cancer. However, blood in the urine can also be a symptom of other conditions so bladder cancers are often missed if the blood in the urine is the only symptom. There is a need for a fast, non-invasive test that can detect bladder cancer at early stages. This study is investigating a new test called Xpert Bladder Cancer Detection, which measures genetic markers of bladder cancer. The researchers want to compare the ability of this new test to detect bladder cancer in patients with blood in the urine, compared to the methods that are currently used. A urine cytology test is currently used, which looks for the presence of abnormal cells in a urine sample.

Who can participate?

Patients who have been referred to the urology clinic with blood in their urine

What does the study involve?

Patient attending the clinic for their cystoscopy procedure will be asked for their permission to collect the leftover urine from this visit. The research team will use the collected sample to assess the new system. The participant will continue with their planned clinic visits and procedures. The research team will collect participants' clinical records such as age, gender, smoking history, current medication, medical history, cytology, cystoscopy, imaging and surgical results.

What are the possible benefits and risks of participating

The research team will only collect the leftover urine, minimising participant involvement and risk. Participants will not benefit directly from taking part in this study. The test result will not be used in the treatment care of the patient and there will be no other test performed on the sample provided. However, participation ensures that the researchers progress in the understanding, design and development of a technique which could support the current recommended procedure for bladder cancer diagnosis. Participation will not change

participants' planned care and they will be expected to attend all their scheduled clinic appointments.

Where is the study run from?

Perth Royal Infirmary and Ninewells Hospital (UK)

When is the study starting and how long is it expected to run for?

January 2021 to August 2023

Who is funding the study?

Cepheid Solutions (USA)

Who is the main contact?

Prof. Ghulam Nabi

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Contact information

Type(s)

Public

Contact name

Prof Ghulam Nabi

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

273366

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 273366

Study information

Scientific Title

Verification of urinary Xpert bladder cancer detection test in patients with haematuria

Acronym

VIXEN

Study objectives

The aim of this study is to test a new bladder cancer detection machine and to determine if this is better than currently used bladder cancer detection methods.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/02/2020, South West - Central Bristol Research Ethics Committee (Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT, UK; +44 (0)207 1048029; centralbristol.rec@hra.nhs.uk), REC ref: 20/SW/0040

Study design

Prospective single-centre observational cohort trial

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Suspected bladder cancer

Interventions

Patient attending the clinic for their cystoscopy procedure will be asked for their permission to collect the left-over urine from this visit. The research team will use the collected sample to assess the new non-invasive system for its diagnostic accuracy. The participant will continue with their planned clinic visits and procedures as per their clinical pathway. The research team will collect participants clinical records such as age, gender, smoking history, current medication, medical history, cytology, cystoscopy, imaging and surgical results.

Intervention Type

Other

Primary outcome(s)

Performance characteristics of Xpert Detection on the GeneXpert Instrument Systems in comparison to the methods currently used at the site for detecting bladder cancer in patients with haematuria:

1. The number of patients correctly diagnosed with bladder cancer in comparison to the Xpert bladder test (true positive)
2. Sensitivity/specificity of the new index test in comparison to histopathology. Sensitivity will use histopathology as standard. Specificity will be calculated by the ability of the Xpert bladder test to rule out false positives in a clinical setting.

Measured at 18 months

Key secondary outcome(s)

Comparison of the total cost of both diagnosis (cystoscopy and cytology) strategies (with or without Xpert Bladder Cancer Detection), measured at 18 months

Completion date

31/08/2023

Eligibility

Key inclusion criteria

1. Adults over the age of 18
2. Presenting with visible and non-visible haematuria within 12 weeks of the consent visit
3. Scheduled for a standard of care cystoscopy
4. Agrees to provide voided urine for trial purposes
5. Able to consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Previous diagnosis of bladder cancer
2. Previous history of kidney stone
3. Indwelling urethral catheter
4. Ongoing urinary tract infection
5. Not able to consent

Date of first enrolment

01/01/2020

Date of final enrolment

30/07/2023

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
NHS Tayside
Ninewells Hospital & Medical School
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee

ROR
<https://ror.org/03h2bxq36>

Funder(s)

Funder type
Industry

Funder Name
Cepheid Solutions

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Ghulam Nabi (g.nabi@dundee.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No