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Urinary Xpert bladder cancer detection test in patients with haematuria

Submission date
03/11/2020

Recruitment status
No longer recruiting

Registration date
23/12/2020

Overall study status
Completed

Last Edited
27/01/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
273366

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

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

Overall study start date
01/01/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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
Scotland

United Kingdom

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

Sponsor information

Organisation
University of Dundee

Sponsor details
Tayside Medical Science Centre
Ninewells Hospital and Medical School
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Sponsor type
University/education

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

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Industry

Funder Name
Cepheid Solutions

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2023

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