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Xpert bladder cancer monitor test for bladder cancer surveillance

Submission date
11/03/2017

Recruitment status
No longer recruiting

Registration date
15/03/2017

Overall study status
Completed

Last Edited
25/09/2017

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bladder cancer is one of the most common types of cancer worldwide. The most common type of bladder cancer is non-muscle invasive bladder cancer (NMIBC) and accounts for around 75% of all newly diagnosed cases. This is where the tumor is confined to the bladder and has not spread to other parts of the body. In patients who have had a bladder tumour removed, they are usually followed up regularly in order to make sure the cancer has not returned. This is done using a procedure called white-light imaging (WLI) cystoscopy, in which a cystoscope (a thin, lighted tube with a lens) is passed up through the urethra (the tube through which you urinate). The bladder is then filled with water or saltwater solution in order to stretch the bladder walls to identify suspicious lesions (damaged areas). This procedure has to be done regularly, which can be inconvenient and uncomfortable for patients. The Xpert® Bladder Cancer Monitor is a device which tests whether certain chemical indicators (biomarkers) are present in urine which could suggest that the cancer has come back. The aim of this study is to find out whether monitoring patients with the Xpert® Bladder Cancer Monitor is as accurate as regular cystoscopies.

Who can participate?
Adults who have a previous history of non-muscle invasive bladder cancer

What does the study involve?
Participants attend routine monitoring appointments as they would usually (every three months for the first two years after first diagnosis of bladder cancer, then every six months for the fifth year, and yearly thereafter). At these appointments, patients undergo a cystoscopy, which involves a thin, lighted tube with a lens being passed up through the urethra (the tube through which you urinate) into the bladder to, and urinary cytology, which involves testing urine for abnormal cells that could suggest the cancer has come back. Participants also provide a urine sample with is then tested in the Xpert Bladder Cancer Monitor for markers that the cancer has come back. The results of the usual tests and the new test with the Xpert Bladder Cancer Monitor are then compared to find out how accurate the Xpert Bladder Cancer Monitor is.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Medical University Innsbruck (Austria)

When is the study starting and how long is it expected to run for?
September 2016 to December 2018

Who is funding the study?
Medical University Innsbruck (Austria)

Who is the main contact?
Dr Renate Pichler
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Contact information

Type(s)
Scientific

Contact name
Dr Renate Pichler

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Xpert bladder cancer monitor for the surveillance of patients with a previous history of non-muscle invasive bladder cancer: a diagnostic accuracy study

Study objectives
The aim of this study is to evaluate the diagnostic accuracy of a novel qualitative in vitro urinary test, the Xpert® Bladder Cancer Monitor, compared to cystoscopy and urinary cytology as the gold standard for bladder cancer surveillance at a single institution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee of the Medical University Innsbruck, 12/05/2016, ref: AN2016-0056; 360 /4.7 and 368/5.12 (3954a)

Study design
Prospective single-centre case series diagnostic accuracy study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Non-muscle invasive bladder cancer

Interventions
Following provision of informed consent to participate, participants attend routine appointments as part of their usual care every three months for the first two years after first diagnosis of bladder cancer, then every six months for the fifth year, and yearly thereafter. At these appointments, participants undergo the following procedures:

Urinary cytology:
Urine cytology is a test to look for abnormal cells in the voided urine and bladder washing. The cytopathological Evaluation will be performed according to the Paris Classification System including 7 diagnostic categories.

Cystoscopy:
A cystoscope is a thin tube with a camera and light on the end. During a cystoscopy, this tube is inserted through the urethra transurethrally and into the bladder, analyzing und visualizing the inside of the bladder. The Urethra is the tube that carries urine out of your bladder. Magnified images from the camera are displayed on a screen where your doctor can see them.

Xpert Bladder Cancer Monitor test:
3 ml of voided urine is inserted in the Xpert reagens kit within one hour after urine sample collection. Then, 4 ml of the mixture is inserted into the self-contained PCR cartridge before the RT-PCR can be started. The results will be provided after approximately 90 minutes. 5 mRNA Targets will be measured by RT-PCR.

Intervention Type
Procedure/Surgery

Primary outcome measure
Diagnostic accuracy of the Xpert Bladder Cancer monitor to detect bladder cancer recurrence is assessed by measuring sensitivity, specificity, NPV and PPV

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Previous history of non-muscle invasive bladder cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Muscle-invasive bladder cancer
2. Primary diagnosis of bladder cancer
3. Aged under 18 years

Date of first enrolment
01/01/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Austria

Study participating centre
Medical University Innsbruck
Department of Urology
Anichstraße 35
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Sponsor information

Organisation
Medical University Innsbruck

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03pt86f80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medical University Innsbruck

Results and Publications

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

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Renate Pichler, Medical University Innsbruck, Department of Urology, Anichstreet 35, A-6020 Innsbruck.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No