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The role of Image Enhancement Systems in the management of patients with non-muscle invasive bladder cancer

Submission date
28/10/2016

Recruitment status
No longer recruiting

Registration date
03/11/2016

Overall study status
Completed

Last Edited
03/11/2016

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
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 inner surface of the bladder, without spreading deeply in the bladder wall or to other parts of the body. Patients with NMIBC are submitted to tumor removal through their urethra (the tube through which urine passes) and the procedure is called transurethral resection of NMIBC (TUR-NMIBC), in which an instrument called resectoscope (a lighted tube with a lens and a loop-shaped wire on its tip) is passed up through the urethra and the loop-shaped wire cuts the tumor into small chips with the use of electric current. Depending on the pathology results of the resected (removed) tumor, some patients may have to regularly receive additional treatment (medications placed in the bladder) and also 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 bladder is then filled with water or saltwater solution in order to stretch the bladder walls to identify suspicious lesions (damaged areas). In recent years, new techniques have been developed in order to try and improve the accuracy of the detection and identification of these lesions. The Storz Professional Image Enhancement System (SPIES) is a new product which is designed to give a clearer image in a cystoscopy than the traditional white-light cystoscope. The aim of this study is to find out whether SPIES cystoscopy is able to detect suspicious bladder lesions more effectively than WLI cystoscopy.

Who can participate?
Adult patients who have had a NMIBC previously removed.

What does the study involve?
At the beginning of each visit for cystoscopy, each patient undergoes both WLI cystoscopy and SPIES cystoscopy conducted by two urologists. Each urologist performs one type of cystoscopy (either WLI or SPIES) in each patient. Each examiner does not know the results of his colleague. Each patient continues to be assessed with cystoscopies performed in the same way after 3, 6, 9,

12, 18, and 24 months. If a patient is diagnosed with a new tumor at any time during the follow up period, he/she undergoes TUR-NMIBC and further follow up in terms of this study is stopped.

What are the possible benefits and risks of participating?
Patients may benefit from a more accurate diagnosis of their suspicious bladder lesions which could lead to better treatment. There are no risks involved for patients taking part in this study.

Where is the study run from?
University of Crete, Medical School (Greece)

When is the study starting and how long is it expected to run for?
December 2015 to December 2019

Who is funding the study?
University General Hospital of Heraklion (Greece)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
White light imaging vs. Storz Professional Image Enhancement System (SPIES) cystoscopy during follow up of patients submitted to White light – transurethral resection of non-muscle-invasive bladder cancer: A randomized diagnostic trial

Acronym
SPIES

Study objectives
The aim of this study is to evaluate whether the follow up of patients submitted to White light – transurethral resection of non-muscle-invasive bladder cancer (TUR-NMIBC) is more accurate when performed using the Storz Professional Image Enhancement System (SPIES) cystoscopy compared to conventional white light (WLI) cystoscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University General Hospital of Heraklion, Crete, Greece, 19/02/2015, ref: 17968/19-02-2015

Study design
Case series diagnostic accuracy study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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

Interventions
All patients with suspected or confirmed NMIBC submitted to (TUR-NMIBC) using WLI (WLI-TUR-NMIBC) fulfilling specific inclusion criteria will be consecutively and prospectively recruited in the study. Medical history including demographic characteristics, intraoperative findings and pathology reports will be recorded. Participants will be submitted to the typical adjuvant treatment (intravesical chemotherapy or bacillus Calmette-Guérin (BCG) immunotherapy), if needed, according to the current guidelines.

Each patient will be followed-up by an intensive cystoscopy visit schedule. The first follow up cystoscopy visit will take place performed at 3 months after the operation (WLI-TUR-NMIBC). Each patient will afterwards followed up by cystoscopy visits at 3, 6, 9, 12, 18 and 24 month postoperatively. At the beginning of each cystoscopy visit, each patient will undergo both WLI cystoscopy (reference standard test) and SPIES cystoscopy (index test) conducted by two experienced urologists at the same session (without any washout period between tests).

Each examiner will perform one type of cystoscopy (either WLI or SPIES) in each patient. For each patient, a web-based randomization protocol will be used to define the type of cystoscopy (WLI or SPIES) each examiner will conduct (in a randomized sequence). Each examiner, will be blinded to his colleague's results, and will fill in a pre-defined bladder diagram form. Bladder washout samples will be obtained at the end of each cystoscopy for cytological examination. Patients with tumor recurrence/suspicious lesions will either undergo TUR-NMIBC and/or targeted biopsies (further follow up in terms of this study will stop) or will be marked for further reviewing. Same equipment will be used in all cases (cysto-urethro flexible or rigid fiberoscope (Karl Storz, Tuttlingen, Germany), IMAGE 1 Storz Professional IES platform (SPIESTM; Karl Storz, Tuttlingen, Germany)).

Intervention Type
Device

Primary outcome measure
Recurrence rate detection of both the reference and index tests, using positive values for tumour recurrence and negative values for no tumour reoccurrence at 3, 9, 12, 18 and 24 months after WLI-TUR-NMIBC.

Secondary outcome measures
To evaluate the contribution of each cystoscopy type (WLI vs SPIES) in the diagnosis of NMIBC in patients with positive urine cytology, via comparison of diagnosis rates between the two tests

Overall study start date
19/02/2015

Completion date
19/02/2019

Eligibility

Key inclusion criteria
Patients with suspected or confirmed NMIBC fulfilling the following inclusion criteria will be prospectively recruited in the study:
1. Prior WLI-TUR-NMIBC of primary or recurrent tumor(s)
2. Age ≥18 years
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The target sample size has being calculated to be 211 patients

Key exclusion criteria
1. Participation in a similar protocol
2. Absence of upper urinary tract tumors
3. Pregnancy/breastfeeding

Date of first enrolment
20/02/2015

Date of final enrolment
20/02/2015

Locations

Countries of recruitment
Greece

Study participating centre
University General Hospital of Heraklion
Department of Urology
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Sponsor information

Organisation
University of Crete, Medical School

Sponsor details
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71003

Sponsor type

University/education

Website
http://www.med.uoc.gr/

ROR
https://ror.org/00dr28g20

Funder(s)

Funder type
Not defined

Funder Name
University of Crete, Medical School

Results and Publications

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

Intention to publish date
19/02/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration