

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/11/2016	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

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

Contact name

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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

University of Crete Medical School

Heraklion, Crete

Greece

71500

Sponsor information**Organisation**

University of Crete, Medical School

Sponsor details

Voutes

Heraklion, Crete

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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