

The contribution of endoscopic image enhancement systems in the management of superficial bladder cancer

Submission date 22/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/04/2016	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 bladder and has not spread to other parts of the body. In patients who have had a bladder tumor 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). 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?

Doctors specializing in the urinary tract system (urologists) and patients with suspicious bladder lesions as identified in a cystoscopy.

What does the study involve?

Each patient undergoes a cystoscopy which will capture images of the inside of the bladder using both WLI and SPIES modes. These images are then placed on an internet-based platform in a random order (so it is not known which technique was used to capture which image). Urologists and urologists in training who are taking part then are asked to vote on six pairs of images in order to find out which they think is the best quality image and which they think were taken using the WLI and SPIES techniques respectively.

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?
March 2015 to August 2015

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

Subjective image quality assessment of Storz Professional Image Enhancement System (SPIES) cystoscopy in patients with non-muscle-invasive bladder cancer (NMIBC): A nation-wide survey

Acronym

SPIES

Study objectives

The aim of this study is to evaluate whether SPIES cystoscopy provides a better subjective viewing experience 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

Single-centre case series diagnostic accuracy study

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Internet/virtual

Study type(s)

Diagnostic

Participant information sheet

Available in Greek at <http://goo.gl/forms/pQ6UaeXTx9>

Health condition(s) or problem(s) studied

Non-muscle-invasive bladder cancer (NMIBC)

Interventions

All images used for this study are captured during cystoscopy of patients with suspicious bladder lesions, as a standard diagnostic procedure. Concretely, patients scheduled for an outpatient diagnostic cystoscopy who are found during the procedure to carry suspicious bladder lesions, are randomly selected to participate in the study. After giving informed consent, each patient is submitted to cystoscopy using the Storz Professional Image Enhancement System (SPIES) with SPIESVIEW option. SPIES is a novel system of digital image enhancement that potentially improves clarity during cystoscopy. It uses the different light wavelengths to produce images with different contrast specifications without the need of an endoscopic filter use, and can potentially result in a more detailed endoscopic viewing. On the contrary WLI cystoscopy records standard images of the bladder wall without any alteration. Two representative images of the suspicious bladder lesions are selected per patient and captured using WLI and SPECTRA B modes simultaneously. Non-processed images are in a within pair random-per-modality fashion placed in an on-line survey platform. All registered members of the Hellenic Urological

Association (HUA) are officially invited by two consecutive e-mails to participate in the survey. Each participant is asked to securely provide their e-mail for authentication purposes and vote on 6 pairs of images consecutively, without being able to modify their answers. Participants are asked blindly to the image mode used, to score each image using absolute category rating (ACR) on a scale ranging from 1 (bad quality) to 5 (excellent quality). The test is performed using a modified for images double stimulus continuous quality scale (DSCQS) method as the standard for subjective video quality tests.

Intervention Type

Device

Primary outcome measure

Image quality is measured using absolute category rating (ACR) following the diagnostic imaging. ACR was based on a modified-for-images, double stimulus, continuous quality scale (DSCQS) method (the standard for subjective video quality tests). Mean opinion scores (MOS) on the ACR scale are compared between the SPIES cystoscopy group and the WLI cystoscopy group.

Secondary outcome measures

Correlation of the difference in MOS (DMOS) of the two groups with demographic data of study participants (age, medical status, sex, and previous experience with image enhancement systems for the diagnosis of NMIBC)

Overall study start date

01/03/2015

Completion date

31/08/2015

Eligibility

Key inclusion criteria

Health professional inclusion criteria:

All registered members of the HUA (urologists and residents in urology)

Patient inclusion criteria:

1. Patients with a formal indication for an outpatient diagnostic cystoscopy at our department (such as suspicion of bladder tumor, or patients on a regular follow up after bladder tumor resection)
2. Those who were found during the procedure (outpatient diagnostic cystoscopy) to carry suspicious bladder lesion(s)
3. Provision of informed consent

Participant type(s)

Health professional

Age group

All

Sex

Both

Target number of participants

634

Key exclusion criteria

Health professional exclusion criteria:

Not meeting the inclusion criteria.

Patient exclusion criteria:

1. No indication for an outpatient diagnostic cystoscopy at our department (e.g. healthy volunteers),
2. No suspicious bladder lesion during the procedure (outpatient diagnostic cystoscopy)
3. Not providing informed consent

Date of first enrolment

01/04/2015

Date of final enrolment

31/05/2015

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

Greece

71003

Sponsor type

University/education

Website

http://www.med.uoc.gr/index_en.php

ROR

<https://ror.org/00dr28g20>

Funder(s)

Funder type

University/education

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

31/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request