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

Submission date 22/02/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 02/05/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 22/04/2016	**Condition category** Cancer	[_] 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 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 cyctoscopy 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 dianostic 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 dianostic 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
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Sponsor information

Organisation
University of Crete, Medical School

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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