Feasibility of confocal laser endomicroscopy in bladder cancer digsnosis

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To directly correlate CLE images with histopathology, and identify and define CLE characteristics of normal urothelium, benign bladder urothelium, and bladder tumors (low-grade, high-grade NMIBC or CIS) of the lower urinary tract.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45769

Source
ToetsingOnline

Brief title
CLE in lower urinary tract

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Bladder and bladder neck disorders (excl calculi)

Synonym
Bladder cancer, urothelial carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Urologie
Source(s) of monetary or material Support: Stichting Cure for Cancer

Intervention

Keyword: bladder cancer, CLE, Lower urinary tract, urothelial neoplasm

Outcome measures

Primary outcome

To describe characteristics and define interpretation criteria for CLE imaging,

based on direct histopathology correlation of:

- Normal or benign bladder tissue

- Urothelial carcinoma

- Low-grade, high-grade NMIBC or CIS

Secondary outcome

To develop a CLE image atlas for bladder tumors, benign bladder urothelium and

normal urothelium of the lower urinary tract

Study description

Background summary

Cystoscopy and cytology, the current *gold standard* for detection and follow-up of primary and recurrent bladder cancer have some limitations. CLE, a high resolution imaging technique, that can be used combined with endo-urological procedures, seems promising to improve diagnosis of bladder cancer. The diagnostic accuracy of cystoscopic applied CLE still has to be defined.

Study objective

To directly correlate CLE images with histopathology, and identify and define CLE characteristics of normal urothelium, benign bladder urothelium, and bladder tumors (low-grade, high-grade NMIBC or CIS) of the lower urinary tract.

Study design

This is a prospective, multicenter, observational study. Diagnostic accuracy of

CLE will be established by comparing CLE diagnosis with pathological diagnosis, the reference standard.

Study burden and risks

A participating patient will not benefit from this study. However, the results of this study may benefit the diagnostic procedure for bladder tumors in the future. There is little burden related to study participation. During TURB (standard procedure), before tumor resection the CLE probe will be held in direct contact with the bladder tumor to obtain CLE images. Before image acquisition we administer fluorescein, which is a commonly used fluorescent dye. In patients not at risk for a demonstrated allergic reaction to this dye this is safe. Patients with a known allergic reaction to fluorescein cannot participate in this study. Aside from tumor resection, a small chip of normal urothelium will be resected. This will act as a control and is included in the CLE atlas. The risks for resecting this extra chip of tissue are minimal.
The estimated prolonged time per-operatively is approximately 15 minutes. Adverse events are not expected. Standard care and pathological evaluation as stated by the hospitals* internal protocol will not be affected by this study.
In conclusion, we believe that the burden and risk associated with participation in this study are low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients >18 years old
- Bladder tumor(s) or possible CIS
- Candidate for TURB
- Signed informed consent

Exclusion criteria

- Patients <18 years old
- Patients with known allergy for fluorescein
- Possible pregnancy or lactating women
- No signed informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2016
Enrollment:	72
Type:	Actual

Medical products/devices used

Generic name:	Confocal Laser Endomicrosopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT03013894
CCMO	NL55537.018.15