# Feasibility of confocal laser endomicroscopy in bladder cancer digsnosis

Published: 04-02-2016 Last updated: 19-04-2024

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

1 - Feasibility of confocal laser endomicroscopy in bladder cancer digsnosis 3-05-2025

#### 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

2 - Feasibility of confocal laser endomicroscopy in bladder cancer digsnosis 3-05-2025

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**

#### **Public**

Selecteer

Meibergdreef 9 Amsterdam 1105 AZ NL

#### **Scientific**

Selecteer

Meibergdreef 9 Amsterdam 1105 AZ NL

# **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