

# Value of optical coherence tomography in the diagnosis of upper urinary tract urothelial carcinoma \* a prospective In-Vivo human study to assess the diagnostic accuracy of optical coherence tomography for diagnosis of upper urinary tract urothelial carcinoma

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To establish in vivo sensitivity and specificity of OCT in the diagnosis of Upper Urinary Tract Urothelial Carcinoma

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

## Summary

### ID

NL-OMON39605

### Source

ToetsingOnline

### Brief title

Diagnostic accuracy of OCT in upper urinary tract urothelial carcinoma.

### Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Ureteric disorders

### Synonym

upper urinary tract tumour, urothelial carcinoma

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** stichting Cure for Cancer;Stichting Urologie 1973

## Intervention

**Keyword:** Diagnostic value, OCT, Upper urinary tract, Urothelial neoplasm

## Outcome measures

### Primary outcome

Diagnosis based on OCT image: parameters are normal urothelium and urothelial carcinoma

### Secondary outcome

Optical properties ( $\mu$ opt) of cancerous tissue and healthy tissue for (1300) nm in the diagnosis of urothelial carcinoma of the upper urinary tract.

## Study description

### Background summary

Recently conservative endoscopic treatment for Upper Urinary Tract Urothelial Carcinoma has been accepted instead of radical nephroureterectomy for patients with low grade, low stage disease. For this reason, knowledge of tumour stage and grade is imminent for clinical decision. Diagnostic ureteropyeloscopy combined with histology is for now the golden standard. Unfortunately is histology often inconclusive.

Optical Coherence Tomography is a new high resolution imaging technique which has the potential to provide the urologist real time per-operative information of grade and stage of the disease.

### Study objective

To establish in vivo sensitivity and specificity of OCT in the diagnosis of

### Study design

This study is a prospective observational human in vivo study. Diagnostic accuracy of OCT will be established by comparing OCT diagnosis with pathological diagnosis, the reference standard.

### Intervention

Single OCT measurement of the ureter using an OCT probe which is introduced via the worksheet of an ureteropyeloscope.

### Study burden and risks

Per-operative a single OCT measurement of the ureter and/or pyelum will be performed. After the OCT measurement, will the ureteropyeloscopy be continued in the usual manner. An OCT measurement will take a maximum of 10 minutes. The extent of burden for the patients is the additional time of surgery. There are no anticipated risks for participating patients since the OCT probe is introduced via the working channel of the ureterorenoscoop (no additional instrumentation). OCT is based on the interaction of tissue and light and is harmless to the patient.

## Contacts

### Public

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### Scientific

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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

Candidate for a diagnostic or therapeutic ureteropyeloscopy because of upper urinary tract tumour.

Signed informed consent

### Exclusion criteria

Patients < 18 years

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): 02-09-2013

Enrollment: 25

Type:

Actual

## Ethics review

Approved WMO

Date:

02-09-2013

Application type:

First submission

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**

CCMO

NL42100.018.12