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

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-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 (µoct) 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 nefroureterectomy 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

Upper Urinary Tract Urothelial Carcinoma

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

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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