The value of confocal laser endomicroscopy in the diagnosis of upper tract urothelial carcinoma * a prospective In-Vivo human pilot to define CLE characteristics of upper tract urothelial carcinoma

Published: 16-08-2016
Last updated: 19-04-2024

To establish in vivo CLE characteristics 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-OMON45090

Source
ToetsingOnline

Brief title
CLE characteristics of UTUC

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

Intervention

Keyword: CLE, Diagnostic, Upper urinary tract, Urothelial neoplasm

Outcome measures

Primary outcome

Diagnosis based on CLE: parameters are normal urothelium and urothelial

carcinoma

Secondary outcome

Tumor grade; low grade or high grade urothelial carcinoma

Study description

Background summary

Recently conservative endoscopic treatment for Upper Urinary Tract Urothelial Carcinoma has been accepted instead of radical nefroureterectomy (the golden standard) for patients with low grade, low stage disease. For this reason, knowledge of tumour stage and grade is imminent for clinical decision. Diagnostic ureterorenoscopy combined with histology (biopsy) is for now the golden standard. Unfortunately histology often is inconclusive.
Confocal Laser Endomicroscopy is a new high resolution imaging technique which has the potential to provide the urologist real time per-operative information of the tumour-grade.

Study objective

To establish in vivo CLE characteristics of Upper Urinary Tract Urothelial Carcinoma

Study design

This study is a prospective observational human in vivo pilot study. CLE images will be correlated with the histopathological diagnosis and the pathological

diagnosis, the reference standard.

Study burden and risks

Per-operative a single CLE measurement will be performed after a single intraureteral administration of fluorescein through the ureterorenoscope. After the CLE measurement, the ureterorenoscopy will be continued in the usual manner. An CLE 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 CLE probe is introduced via the working channel of the ureterorenoscoop (no additional instrumentation). The results of the CLE measurement do not have any influence on the standard diagnostics and treatment of the patiënt.
If the presence of the preoperatively suspect tumour is not confirmed during the diagnostic URS, no study-related activities will be performed in these cases. This means that there is no burden related to study participation for these patients. Standard care and pathological evaluation as stated by the hospitals internal protocol will not be affected.

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 an upper urinary tract tumour.
- Signed informed consent

Exclusion criteria

- Patients <18 years
- Patients with known allergy for fluorescein
- Possible pregnancy or lactating women
- Patients not eligible for radical treatment of an upper urinary tract urothelial carcinoma
- 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):	29-08-2016
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	confocal laser endomicroscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2017
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
CCMO	NL52989.018.16