A prospective, comparative single center study of Hexvix® fluorescence uretero-renoscopy and white light uretero-renoscopy in the detection of upper urinary tract urothelial cell carcinoma

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

Summary

ID

NL-OMON32388

Source
ToetsingOnline

Brief title
White and blue light uretero-renoscopy for the upper urinary tract

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal and urinary tract therapeutic procedures

Synonym
pyelum tumors, ureter tumors

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,GE Healthcare

Intervention

Keyword: Hexvix®, upper urinary tract, uretero-renoscopy, urothelial cell carcinoma

Outcome measures

Primary outcome

-The number of patients with histology-confirmed tumors found by blue light URS

Secondary outcome

All lesions must be histologically confirmed:

-The proportion of patients with tumor(s) found by blue light URS, but not on

white light (fiberoptic or digital) URS

-The proportion of patients with tumor(s) found by white light (fiberoptic or

digital) URS, but not on blue light URS

-The proportion of false-positive lesions on blue light URS and white light

(fiberoptic or digital) URS

-The detection rate of white light (fiberoptic or digital) URS combined with

blue light URS for patients with tumor(s).

-Registration of adverse events

Study description

Background summary

The detection of urothelial cell carcinoma (UCC) in the upper urinary tract is

suboptimal, as malignant lesions are easily missed by the currently considered golden standard: digital white light uretero-renoscopy (URS) (previously, the golden standard was white light fiberoptic URS). Blue light (fluorescence) cystoscopy in combination with administration of photoactive porphyrins (Hexvix®) has improved the detection of non-muscle invasive bladder UCC. In this study we use the same technique for the upper urinary tract (UUT), by using a blue light URS, in order to improve the detection rate of UCC in the UUT.

Study objective

Primary objective is to investigate the feasibility of Hexvix® blue light URS. Secondary objectives are to determine the diagnostic value of Hexvix® blue light URS as compared to digital and fiberoptic white light URS, and to assess safety and toxicity of Hexvix® administered to the upper urinary tract.

Study design

prospective, comparative, single center study (Radboud University Nijmegen Medical Centre), exploring the feasibility of blue light URS, and comparing blue light fiberoptic URS with digital and fiberoptic white light URS in the detection of urothelial cell carcinoma (UCC) of the upper urinary tract (UUT), in 15 patients with known UCC or suspicion for UCC of the proximal ureter and/or pyelum. Expected time needed for inclusion: 1 year.

Patients undergo both digital white light uretero-renoscopy (URS) (part of routine medical treatment) as well as blue light fiberoptic URS preceded by titration of 42.5 mg Hexvix®/20 ml solvent for 30 minutes in both ureters/pyela (this is extra for study purposes). Any lesion suspect for UCC will be biopsied.

Study burden and risks

Risks: -prolonged operation time of approximately 45 minutes
-side-effects of Hexvix®
Benefits: -possibly better detection of UCC
-possibly more radical resection of UCC
Hexvix® is registered for intravesical administration, and has less side-effects than other for the bladder registered drugs: mitomycin-C (chemotherapy) or BCG (immunotherapy). Mitomycin-C and BCG can safely be applied to the upper urinary tract. We expect the same for Hexvix®.

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 with known urothelial cell carcinoma (UCC) of the upper urinary tract (UUT)
-Patients with suspicion for UCC of the UUT based on one of the following:
-unilateral or bilateral ureter sampling (suspect or malignant cells on cytology)
-suspect or malignant cells on urine cytology, with negative bladder biopsies
-macroscopic tumor on previous uretero-renoscopy
-tumor seen on imaging techniques (ultrasound, IVP, CT, MRI)
-Patients with ZUBROD-ECOG-WHO performance status of 0-2
-Patients must be over 18 years of age
-Patients must be fully informed of the investigational nature of the study and signed written informed consent must be obtained prior to any study specific investigations

Exclusion criteria

-Patients with existing or recurrent severe urinary tract infection
-Gross haematuria (defined as heavy bleed resulting in marked amounts of blood in the urine, which may interfere with fluorescence uretero-renoscopy. Where the bleed is light, the patient should not be excluded if in the investigator*s opinion rinsing during uretero-renoscopy will alleviate the possible interference with fluorescence cystoscopy)
-Patients with porphyria
-Known allergy to hexyl aminolevulinate hydrochloride or a similar compound
-Pregnant or breast-feeding (patients must use adequate birth control methods while on the study and for 4 weeks following the end of treatment)
-Patients who have received BCG or chemotherapy in the UUT within 3 months prior to uretero-renoscopy
-Conditions associated with a risk of poor protocol compliance

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Hexvix
Generic name:	hexaminolevulinate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-12-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2007-005403-17-NL
CCMO	NL19885.091.07