Optical biopsy to improve the diagnosis of kidney cancer: a prospective, observational, multicentre, in-vivo study.

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To evaluate the accuracy and adverse events of combined use of minimal invasive optical coherence tomography (OCT) to differentiate normal tissue from (different types of) malignant tissue in kidneys.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON39685

Source
ToetsingOnline

Brief title
Optical biopsy to improve the diagnosis of kidney cancer

Condition

- Renal disorders (excl nephropathies)

Synonym
Kidney cancer, renal mass

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF (ingediend)

Intervention

Keyword: OCT, Optical biopsy, Renal cell carcinoma

Outcome measures

Primary outcome

Primary parameter

To determine the accuracy of OB to differentiate renal tumor pathology from benign tissue by means of minimal invasive quantitative optical coherence tomography and diffuse reflectance spectroscopy.

Secondary outcome

Secondary parameters

- To determine the differentiation capability of this combined technique to distinguish between the three most common RCC sub-types.

- To determine whether OB is a good alternative to percutaneous biopsy for the diagnosing of renal cancer based upon accuracy and cost-effectiveness.

Study description

Background summary

Renal biopsies are used in patients with renal mass lesions to diagnose whether it concerns a malignant or benign mass. In case of malignancy, surgery will be the following step. However, 7 to 33% of biopsies are non-diagnostic, what can result in unnecessary surgery (even up to 30% in small renal masses). We believe that optical biopsy (OB), a new diagnostic tool based on the absorption en reflection of light in tissues, reduces the non-diagnostic biopsy rate. This could have a direct impact on the quality of life of the patients that are therefore scheduled for an unnecessary surgical procedure. Also, concerns about overtreatment have led to the concept of focal therapy, a selective patient tailored ablation technique of a lesion, reducing lifetime morbidity and side effects without compromising life expectancy. For this novel form of treatment, accurate identification, grading and demarcation of a lesion is crucial and OB

is the ideal platform to provide this approach to an improved cure.

Study objective

To evaluate the accuracy and adverse events of combined use of minimal invasive optical coherence tomography (OCT) to differentiate normal tissue from (different types of) malignant tissue in kidneys.

Study design

This is a prospective, observational, blinded, multicentre, in-vivo study in a cohort of 194 patients with the clinical diagnostics of a renal mass. All consecutive patients scheduled for nephrectomy, partial nephrectomy or cryo ablation due to a renal mass will be enrolled in this study until the required sample size is reached. Inclusion is based on informed consent approval and conjoint availability of the departments of Pathology and Biomedical Engineering & Physics (BMEP) at time of surgery. The only interaction with patients is during biopsy and surgery. Results of OCT and DRS will not interfere in the regular follow-up according to histopathological diagnosis and institutional protocol.

The study is roughly divided into three different steps:

First, calibration of the OCT systems will be performed to confirm the tissue related quantitative optical parameters that are extracted from OCT measurements. Both systems will be simultaneously calibrated using tissue mimicking optical phantoms.

Second, optical biopsies will be taken in all of the 194 patients in whom a solid renal mass was seen by cross-sectional imaging. The optical biopsies, with a minimum of 5 measurements per biopsy spot, will be obtained. After this procedure, conventional needle biopsy of the kidney tumors will be obtained with a minimum of 2 biopsies. These procedures will be repeated in a subgroup of 30 patiënts during surgical removal of the tumor. This provides control data on previous findings and evaluates applicability during surgery at the OR. Outcomes of the optical biopsies are correlated to pathology.

Third, in cases with confirmed malignancy, the discriminating ability of optical biopsy among the three most common RCC sub types will be blindly assessed. The previously established protocol will be used and optical biopsy outcomes will be correlated to pathological findings.

Study burden and risks

There are no anticipated additional risks for participants since the OCT is a non-invasive imaging method based on light. However, during the percutaneous

biopsy a slightly larger canule is necessary to access the retro-peritoneal cavity since the percutaneous needle device has no entrance for an additional probe such as our OCT probe. During operation, the operation time is prolonged for only a couple of minutes (max. 5%).

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

- Age >= 18 years
- Solid, enhancing mass on cross sectional imaging suspect for RCC
- Scheduled for nephrectomy, partial nephrectomy or cryoablation
- Signed informed consent

Exclusion criteria

Patients with a renal mass that are not candidates for active treatment.

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2013
Enrollment:	194
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2014
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	NL41985.018.12