Differentiation between normal renal tissue and renal cell carcinoma using optical coherence tomography (OCT): a prospective human in-vivo study.

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Demonstrate the ability of OCT to distinguish malignant renal tissue from benign (normal) renal tissue by means of attenuation-coefficient.

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

Summary

ID

NL-OMON34505

Source
ToetsingOnline

Brief title
Differentiating renal tumors using in-vivo OCT

Condition

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

Synonym
renal cell cancer, renal mass

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostics, Kidney, OCT, Renal Cell Carcinoma

Outcome measures

Primary outcome

Primary study outcome is the attenuation-coefficient measured by OCT of the 2

tissue types: normal renal parenchyma and malignant (RCC) tissue.

Secondary outcome

None

Study description

Background summary

Differentiation between benign and malignant (small) renal mass by radiological means is difficult and therefore up to 30% of surgery for renal mass is unnecessary. Optical Coherence Tomography (OCT) is a technique that may contribute to improvement of the accuracy of such renal mass.
OCT is an imaging technique analogous to ultrasound exept for the fact that it employs light- in stead of soundwaves. OCT measures the effective reflection of light in dephth of a tissue sample. When a ray of light penetrates into a tissue sample the intensity of the light decreases due to scattering and absorption of light by different structures in the tissue sample (such as nuclei and organelles).

Our hypothesis is that OCT can differentiate malignant from benign tissue by objectivating the decrease of light intensity per milimeter, since the attenuation of light intensity is hypothetically higer in malignant tissue due to the larger size and amount of nuclei and organelles whch results in a higer degree of scattering and absorption of light. This attenuation is objectivated as the attenuation-coefficient (or µt).

Study objective

Demonstrate the ability of OCT to distinguish malignant renal tissue from

benign (normal) renal tissue by means of attenuation-coefficient.

Study design

This study is an observational cohort-study with patients scheduled for surgery for a renal mass suspect for malignancy.

Study burden and risks

OCT is harmless for human beings since it is light-based with a wavelength of 1300 nm.
Since all measurements take place during surgery there are no extra visits necessary.
The operation time is slightly prolonged (max. 5 minutes with a (partial) nephrectomy usually taking about 2 hours of operation time).

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

> 18 yrs
solid, enhancing renal mass, suspect for malignancy
scheduled for (open or laparoscopic) nephrectomy or partial nephrectomy
signed informed consent

Exclusion criteria

cystic renal mass

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):	01-09-2010
Enrollment:	34
Type:	Anticipated

Medical products/devices used

Generic name:	Optical Coherence Tomograhpy
Registration:	Yes - CE intended use

Ethics review

Approved WMO
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	NL32723.018.10