Using a drop-in probe to conduct optical measurements during robot assisted laparoscopic prostatectomy

Published: 12-03-2021
Last updated: 08-04-2024

To assess the usability of a drop-in optical probe in terms of quality of optical measurements and impact on current workflow.

Ethical review	Approved WMO
Status	Pending
Health condition type	Male genital tract therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON54954

Source
ToetsingOnline

Brief title
Drop-in probe for optical measurements during prostate surgery

Condition

- Male genital tract therapeutic procedures

Synonym
Prostate cancer, Prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diffuse reflectance spectroscopy, margin assessment, prostate carcinoma, surgery

Outcome measures

Primary outcome

The main study parameter is the usability of a drop-in optical probe in terms quality of measurements and impact on current workflow.

To assess the usability of the optical drop-in probe, we want to assess whether the drop-in optical probe can make tissue contact at all prostate surfaces. To measure this, we want to use single fiber reflectance measurements. These single fiber reflectance measurements are performed automatically and simultaneously with the diffuse reflection spectroscopy measurements and measure a high reflection if there is no adequate tissue contact.

Secondary outcome

The secondary study parameter is ease of use of a drop-in DRS probe as reported by surgeons. We intend to use the System Usability Scale (SUS-score) to assess the ease of use as reported by surgeons.

For future research it is important to be able to mark the measurement locations, so that the measurement location can be traced back in pathology slides and so that it can be correlated to the acquired spectra. Therefor in this study we want to assess which method, a suture or a clip, can best be used to mark the measurement location in vivo and to find back the measurement location in the pathology slides.

Study description

Background summary

Differences in optical characteristics between tumorous and healthy tissue allow for the discrimination between tissue types. By performing Diffuse Reflectance Spectroscopy (DRS) measurements at the resection margin, a surgeon can detect and thus minimize positive resection margins during surgery. To use this technique in vivo during Robot Assisted Laparoscopic Prostatectomies (RALP) a drop-in optical DRS was designed.

Study objective

To assess the usability of a drop-in optical probe in terms of quality of optical measurements and impact on current workflow.

Study design

Feasibility study

Study burden and risks

The study population for this study will consist of patients that receive robot assisted laparoscopic prostatectomy for histologically proven prostate carcinoma.
Participation in this study will not involve additional hospital visits, physical examinations or tests, or the completion of questionnaires or diaries for the patient.
The patient can give informed consent during one of the visits to the outpatient clinic.
Measurements will involve the patient*s exposure to harmless light.
The process of measuring will add no more than 15 minutes to the total operation time, during which patients will be under general anaesthesia.

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

Men undergoing robot assisted laparoscopic prostatectomy for * T2 prostate carcinoma, without neoadjuvant therapy

Exclusion criteria

- Suspected oversensitivity to light; e.g. a patient who has had photodynamic therapy
- History of radiotherapy in the pelvic area
- History of abdominal surgery
- History of neoadjuvant androgen deprivation therapy
- Use of indocyanine green (ICG) injections prior to surgery

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Optical spectroscopy drop-in probe
Registration:	No

Ethics review

Approved WMO

Date:	12-03-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL75036.031.20