In-vivo focal prostate imaging with confocal laser endomicroscopy and optical coherence tomography

Published: 07-07-2017
Last updated: 13-04-2024

Objective procedure 1:To assess the technical feasibility and safety of in-vivo focal imaging with CLE and OCT.Objective procedure 2: Primary Objective: To identify and define characteristics of prostate cancer on CLE and OCT and compare this with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Prostatic disorders (excl infections and inflammations)
Study type	Observational invasive

Summary

ID

NL-OMON47550

Source
ToetsingOnline

Brief title
FPI (focal prostate imaging)

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
carcinoma of the prostate, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: STW,Cure for Cancer foundation

Intervention

Keyword: cancer, endomicroscopy, oct, prostate

Outcome measures

Primary outcome

Procedure 1 primary parameters/endpoints:

- Technical feasibility of CLE and OCT in the prostate by transperineal approach

Procedure 2 primary parameters/endpoints:

- In-vivo images made with CLE and OCT of the different tissues in the

prostate, verified by histopathology

Secondary outcome

Procedure 1 secondary parameters/endpoints:

- List of procedure-related adverse events of needle based OCT and CLE

Procedure 2 secondary parameters/endpoints:

- Technical feasibility of CLE and OCT in the prostate by transperineal approach

- List of procedure-related adverse events of needle based OCT and CLE

- Visual descriptive image criteria for CLE and OCT images of the different

prostate tissues

Study description

Background summary

The current limitations in prostate cancer diagnostics lead to over- and undertreatment for a significant fraction of patients. Confocal Laser

Endomicroscopy (CLE) and Optical Coherence Tomography (OCT) are focal imaging modalities with potential for in-vivo prostate imaging. We anticipate that integrating focal imaging with MRI/TRUS fusion will further improve prostate cancer detection and provides a real-time histopathological three-dimensional representation of the tumor lesions.

Study objective

Objective procedure 1:
To assess the technical feasibility and safety of in-vivo focal imaging with CLE and OCT.

Objective procedure 2:
Primary Objective:
To identify and define characteristics of prostate cancer on CLE and OCT and compare this with histology.

Secondary Objective(s):
- To develop the first steps towards an in-vivo CLE and OCT image atlas of the prostate (benign glands, cystous atrophy, regular atrophy, stroma, malignant tissue using the Gleason score, inflammation, fat)
- To assess procedure related adverse events of in-vivo focal imaging by use of Common Terminology Criteria for Adverse Events
- To detect lymph node metastasis (ex-vivo) with CLE after extended pelvic lymph node dissection

Study design

This is an investigator-initiated, prospective in-vivo safety and feasibility study with two procedures.

Procedure 1:
Patients that are indicated for transperineal template mapping biopsies (TTMB) are included for procedure 1 and will receive transperineal CLE or OCT measurements prior to TTMB.
Procedure 1 is to test the technical feasibility and safety of in-vivo focal imaging with CLE and OCT. Only if transperineal CLE or OCT measurements are possible, we proceed with procedure 2.

Procedure 2:
Patients scheduled for a robot-assisted laparoscopic prostatectomy (RALP) will be included in procedure 2 and receive transperineal CLE or OCT measurements prior to their surgery. Results will be correlated with histology by correlating biopsies during the TTMB procedure or with RALP the measurement trajectory will be marked. After the RALP, the prostate will be cut exactly through the measurement trajectory for whole mount coupes.

In high-risk of high-intermediate-risk patients receiving an extended pelvic lymph node dissection with the RALP, ex-vivo CLE measurements will be performed.

Intervention

Transperineal SFR and CLE measurements will be performed directly prior to the surgery procedure or prior to the TTMB. In case of surgery, intraprostatic plastic IV cannulas will be placed for histopathology correlation. Ex-vivo CLE measurements will be performed and if applicable ex-vivo CLE measurements will be performed in lymph nodes after extend pelvic lymph node dissection.

Study burden and risks

For patients included in this feasibility study there is no direct benefit. However, the results of this study are important for patients in the future, diagnosed with prostate cancer. Previous in-vivo studies OCT did not report any adverse events. Previous studies of CLE combined with intravenous administration of fluorescein haven proven to be safe. Patients with a known allergic reaction to fluorescein cannot participate in this study. Both modalities are performed by needle guidance with the same diameter as a normal prostate biopsy gun. Two sterile cannulas, for marking the measurement trajectory, will stay in the prostate during the surgery and will be removed when the prostate is removed. The cannulas harbor a small increased risk for infection . However, antibiotic prophylaxis is administered as standard of care 2 hour prior surgery to reduce the risk of infection. The estimated prolonged time of the procedure is approximately 30 minutes. Standard care and pathological evaluation as stated by the internal protocol will not be affected in this study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For procedure 1: planned for TTMB
For procedure 2: Localized prostate cancer visible on MRI

Exclusion criteria

Patients with a known allergic reaction to fluorescein

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2018

Enrollment:	14
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-10-2019
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	NL57326.018.17