Multiparametric Ultrasound (mpUS) as Imaging Modality for the Detection and Localization of Prostate Cancer

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Primary objective: To validate mpUS as imaging modality for detection and localization of prostate cancer by direct correlation of mpUS imaging and its parameters with histopathology of the resected prostate.Secondary objective: see Protocol paper,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45386

Source
ToetsingOnline

Brief title
mpUS imaging in Prostate Cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF(UVA 2013-5941)

Intervention

Keyword: multiparametric, prostate, prostate cancer, ultrasonography

Outcome measures

Primary outcome

To directly correlate and compare mpUS imaging and its parameters with the

histology of the resected prostate.

Secondary outcome

Secundary study parameters are summarized in the Protocol paper, section 8.

Methods, pag 27 of 42.

Study description

Background summary

The current limitations in prostate cancer diagnostics, due to lack of accuracy of the available techniques, lead to over- and undertreatment for a significant fraction of patients with prostate cancer. Multiparametric ultrasound (mpUS), combining different ultrasound parameters, is a new imaging modality with potential to improve PCa detection and localisation significantly. By correlating and comparing the parameters of mpUS of the prostate with its carcinoma to the histology of the resected prostate we can determine the additional clinical value of mpUS.

Study objective

Primary objective: To validate mpUS as imaging modality for detection and localization of prostate cancer by direct correlation of mpUS imaging and its parameters with histopathology of the resected prostate.
Secondary objective: see Protocol paper, section 2. Objectives, pag 19 of 42.

Study design

Prospective, observational study

Study burden and risks

A participating patient will not benefit from this study. However, the results of this study may benefit the diagnostic procedure for prostate cacer in the future. There is litte burden related to study participation and the nature and extent of the burden and risks associated with participation are considered minimal. For the purpose of this study, there is one hospital visit necessary. Patients need to get an intravenous canula for the contrast enhanced mode. An intravenous canula placement is minimal invasive and without risks, however it could be seen as a burden for some patients. During diagnosis of the prostate cancer the patient has already experienced the usage of ultrasound ot the prostate. It is without any risk but it can be seen as a burden for some patients. The patient will know what to expect and would probably refuse participation if the first ultrasound experience was unpleasent. The risk of contrast agent sonovue is minimal. Literature mentions 1 case of an allergic reaction (0,01%). The most frequently mentioned minor side-effects of microbubble contrast agents are alteration of taste, local pain at the injection site and facial or general flush. These side-effects are transient, mild and rare (1-5%). The results of this study may be important for patients in the future for PCa detection, localization and grading. If cancer can be detected and localized reliable using mpUS imaging, this could have a major impact on prostate cancer health care. In conclusion, we believe that the burden and risk associated with participation in this study are low.

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 * 18 years old
- Biopsy proven prostate carcinoma
- Treatment by (robot laparoscopic) radical prostatectomy
- Signed informed consent

Exclusion criteria

- Patients < 18 years old
- Chemotherapy and/or radiotherapy for prostate cancer
- Hormonal therapy for prostate cancer within 6 months prior to procedure
- Patients with known allergy for Sonovue
- Patients with severe cardiac problems: right-to-left cardiac shunt and/or severe (pulmonal) hypertension and/or use of dobutamine medication
- Patients with Acute Respiratory Distress Syndrome

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-09-2017
Enrollment:	200

Type:	Actual

Medical products/devices used

Generic name:	Ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-04-2018
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	NL58710.018.17