Evaluating Non-invasive Assessment of Staging with 68Ga-PSMA-PET/CT and 7T-MRI of Primary Prostate Cancer

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

Summary

ID

NL-OMON48898

Source
ToetsingOnline

Brief title
ENIGMA study

Condition

- Reproductive neoplasms male malignant and unspecified
- Genitourinary tract disorders NEC

Synonym
Prostate cancer, Prostate malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Urologie
Source(s) of monetary or material Support: KWF/Alpe;Unique High Risk Project

Intervention

Keyword: 68Ga-PSMA-PET/CT, 7T-MRI, Localized disease, Prostate Cancer

Outcome measures

Primary outcome

* To assess the prediction of tumour localisation, extraprostatic extension, metabolism and GS of 7T-MRI for PCa, based on whole-mount histopathology validation after radical prostatectomy.

* To assess the prediction of tumour aggressiveness and detection of metastasis, of 68Ga-PSMA-PET/CT for PCa, based on the SUVmax and SUVmean, compared to whole-mount histopathology validation after radical prostatectomy.

Secondary outcome

* To find metabolic markers to predict/mirror PCa Gleason Score, and to create a Gleason score prediction tool for steering individualized treatment options in future studies.

* To compare radiological results from 3T-MRI with 7T-MRI for the detection of PCa, GS and EPE.

* To assess the ability of 7T-MRI to diagnose extraprostatic extension, by evaluating a threshold value of length of capsular contact of dominant lesions and comparing to whole-mount histopathology validation after radical prostatectomy.

Study description

Background summary

Prostate cancer (PCa) is the fifth most common cancer worldwide. If the tumour is confined to the prostate, patients with high risk localized prostate cancer can be treated with radical prostatectomy (RP). However, patients with extra-prostatic extension (EPE) have an increased risk of positive surgical margins, biochemical recurrence, and metastatic disease. The diagnostic accuracy of MRI for local PCa staging has a high specificity but poor and heterogeneous sensitivity (91% and 57%, respectively). In addition, PCa Gleason score (GS) correlates with tumour aggressiveness, but prostate biopsies can understage the tumour in up to 25-54% of cases due to sampling errors. An improvement in accurate non-invasive assessment of tumour aggressiveness, next to an accurate staging of PCa, is essential for an optimal and adequate treatment plan. Using ultra-high field MRI (i.e. 7-Tesla (7T)-MRI), extra-capsular extension could be evaluated with increased accuracy, as even higher spatial resolutions can be achieved, therefore increasing the sensitivity and EPE detection. In addition, the use of 68Ga-PSMA (Galium-68-Prostate Specific Membrane Antigen) PET/CT (Positron-Emission Tomography) allows to detect metastatic disease with high sensitivity.

Study objective

Primary objective is to assess the prediction of tumour localisation, extraprostatic extension, metabolism and GS of 7T-MRI for PCa, based on anatomical, functional and metabolic imaging compared to whole-mount histopathology validation after radical prostatectomy. In addition, to assess the prediction of tumour aggressiveness and detection of metastasis, of 68Ga-PSMA-PET/CT for PCa, based on the SUVmax and SUVmean, compared to whole-mount histopathology validation after radical prostatectomy.

Study design

Prospective imaging (MRI & PET/CT) study.

Study burden and risks

There are no patient specific risks or benefits by participating in this study, however this study is a required step in improving non-invasive assessment of prostate cancer to distinguish between patients who will be accurately treated by radical prostatectomy and those who will not.

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

- Signed written informed consent
- Patients with clinically intermediate to high-risk localized PCa, who are planned for radical prostatectomy (i.e. Gleason score *3+4<=7).

Exclusion criteria

- Patients who are unwilling or unable to sign written informed consent
- Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht (see Appendix I for the 7T-MRI questionnaire).
- Patients with previous treatment for PCa.
- Patients with a history of radiotherapy to the pelvis.
- Patients who underwent a transurethral resection of the prostate (TURP) or stenting of the prostate

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63273.041.18