Validation of multiparametric MRI with histopathology for prostate cancer

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• Determine the impact of variations in multi-parametric MRI on the prediction of tumor probability

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40322

Source
ToetsingOnline

Brief title
Validation of multiparametric MRI of prostate cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
histopathology, MRI, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: EU Dr. Therapath;FP7;project nr 600852

Intervention

Keyword: MRI, prostate cancer

Outcome measures

Primary outcome

The robustness of multiparametric imaging for planning of dose painting radiotherapy of prostate cancer is investigated. The variation in the prediction of tumor probability is determined in a test-retest setting.

Secondary outcome

• Determine the reproducibility of multi-parametric quantitative MRI

• Determine whether there are differences in reproducibility of multi-parametric quantitative MRI between centers

• Determine the impact of variations in predicted tumor probability on the planned treatment dose

• Validate the predicted tumor probability with whole-mount section histology of prostatectomy specimen

Study description

Background summary

Dose painting is a radiotherapy (RT) technique in which the radiation dose is varied locally according the probability of tumor presence and resistance to treatment. This can be assessed using multiparametric MRI.
In this study, the robustness of multi-parametric MRI for dose painting of prostate cancer is investigated. To this end, the steps that lead from imaging to the creation of a dose painting treatment plan are evaluated.

Study objective

• Determine the impact of variations in multi-parametric MRI on the prediction of tumor probability

Study design

Registration study

Intervention

diagnostic MRI exam will be repeated

Study burden and risks

Patients will undergo the standard MRI exam a second time (combined with another hospital visit if possible). In a standard exam, an endorectal receive coil may be used to obtain optimal signal to noise. This causes mild discomfort for the patient. In the standard exam 15 ml of the contrast agent Dotarem (Gadoteric acid, concentration 0.5M) is administered intravenously. No adverse effects are known of the administration of a second dose one week after the regular exam. But an allergic reaction cannot be ruled out. For patient who underwent the first MRI exam as part of the treatment the repeat of the MRI exam causes a negligible risk for the patient but an allergic reaction is well to treat.

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 with biopsy-proven prostate cancer who are scheduled for a prostatectomy

Exclusion criteria

• Contra-indications for a MRI exam according to the standard protocol for the screening of patients with prostate cancer
• Treatment of prostate cancer prior to the MRI exams
• Prior hormonal therapy
• Prior trans-urethral resection (TURP)
• GFR < 30 ml/min/1,73 m^2

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	03-02-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL46247.031.13