Polyamines detection with MR spectroscopy to increase diagnostic specifity in prostate cancer

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To test the feasibility of translating recent technological advances in MRSI of prostate cancer at 7T to the regular 3T platform to improve the capacity to separate partially overlapping peaks of polyamines from choline and creatine

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

Summary

ID

NL-OMON40868

Source
ToetsingOnline

Brief title
Polyamines in prostate cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate cancer.

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Research afdeling radiotherapie

Intervention

Keyword: MR spectroscopy, Polyamines, Prostate cancer

Outcome measures

Primary outcome

To show the feasibility of acquiring 1H MRSI in prostate with reduced chemical shift artifacts at 3T using the FOCI RF pulses in a editing semi-LASER sequence. Quantification for comparison of the metabolite concentrations will be obtained with the LC model.

Secondary outcome

N.A

Study description

Background summary

Accurate staging of prostate cancer is critical to avoid overtreatment of low-risk or under treatment of high-risk disease. The Gleason score (GS) is a highly prognostic measure of tumor differentiation, sampling errors in biopsy procedures make it hard to identify the most aggressive part of the tissue. MR spectroscopic imaging (MRSI) has proven its value in the diagnosis of prostate cancer. It is particularly beneficial where the specificity of other MRI techniques is poor, such as in the transition zone. However, its use in clinical practice is limited by a poor sensitivity, partly caused by the limited spectral resolution available. Limitations in bandwidth (typically in clinical setups) result in a geometrical mismatch between metabolites. Polyamines (PA) are one of the metabolites present in the prostate, which can have a prognostic value of tumor aggressiveness. The PA are located at 3.1 ppm in the MR spectrum and overlap with creatine (3.0 ppm) and choline (3.2 ppm). Editing MRS sequences allow the single detection of polyamines without contamination of other metabolites. We have previously developed an MRSI sequence with frequency-offset-corrected-inversion (FOCI) pulses at a 7 Tesla MR scanner to increase the bandwidth up to a factor 10. Therefore, the geometric mismatch between metabolites is dramatically reduced.

Study objective

To test the feasibility of translating recent technological advances in MRSI of prostate cancer at 7T to the regular 3T platform to improve the capacity to separate partially overlapping peaks of polyamines from choline and creatine

Study design

To test the feasibility of translating recent technological advances in MRSI of prostate cancer at 7T to the regular 3T platform to improve the capacity to separate partially overlapping peaks of polyamines from choline and creatine.
A group of 10 patients with biopsy-proven prostate cancer scheduled for a diagnostic MRI exam at 3T with an endorectal coil will be scanned, including the newly developed FOCI/editing MRSI sequence.
The duration of the study depends on the patients that are willing to participate in the study. We estimate a maximum duration of half a year.

Intervention

MRSI scan will be extended by 20 minutes

Study burden and risks

MRSI scan will be extended by 20 minutes, which does not involve additional risk.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

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 eligible for a brachytherapy screening MRI exam of the prostate with an endorectal coil.

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, including hormonal therapy and trans-urethral resection (TURP)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	10

Type:	Anticipated

Ethics review

Approved WMO Date:	15-07-2014
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	NL48573.031.14