Prostate Cancer localization with a Multiparametric MR Approach - PCa-MAP -

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To prove the diagnostic accuracy of 3T multi-modality MR imaging (high resolution T2-weighted MRI, DCE-MRI, MRSI and DWI techniques) in distinguishing carcinoma from other prostate tissue. The gold standard for distinguishing the tissue types is the...

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

Summary

ID

NL-OMON33366

Source
ToetsingOnline

Brief title
PCa-MAP

Condition

- Prostatic disorders (excl infections and inflammations)

Synonym
to localize prostate cancer within the prostate

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Siemens,Siemens Medical Solutions;Germany

Intervention

Keyword: functional techniques, MR imaging, prostate cancer, tumor localization

Outcome measures

Primary outcome

To determine the diagnostic accuracy (area under the receiver-operating characteristic curve) of 3-Tesla multi-modality non-endorectal coil (ERC) MR imaging in localizing prostate cancer, by correlating:

a) focal areas of low signal intensity on T2-weighted images;

b) the extent and degree of deviating metabolite ratios derived from MRSI. This can be the choline+creatine/citrate ratio or if possible, the choline / citrate ratio;

c) the extent and degree of apparent diffusion coefficient reduction on DWI;

d) the extent and degree of perfusion abnormality on DCE-MRI;

with the presence or absence of cancer at (reconstructed) whole mount section histopathology.

Hypothesis: 3-Tesla multi-modality non-ERC MR will localize prostate cancer with an accuracy of 85%.

Secondary outcome

Proving that multi-modality MR data allows for predicting tumor grade.

The parameters from the different MR methods for a tumor focus can be correlated to the local Gleason grade of the corresponding lesion in the histopathological specimens.

Study description

Background summary

Prostate cancer is the most frequently diagnosed malignancy and the second most frequent cause of cancer related death in western males. In the diagnosis of prostate cancer digital rectal examination and especially the determination of the blood level of prostate specific antigen (PSA) are important screening tools. Standard sextant transrectal ultrasound (TRUS) guided biopsy of the prostate is the most common method used to detect prostate cancer in patients following an abnormal DRE or high serum PSA levels . Histopathological examination of (TRUS-guided) prostate biopsies remains to be the diagnostic gold standard.

Imaging modalities like TRUS, computed tomography and FDG-PET have proven to be too inaccurate for adequate localization. Conventional T2-weighted MR imaging is also not optimal in this respect. Reported accuracies range from 62 to 72%. Accurate localization of prostate cancer within the prostate has important clinical implications. More accurate cancer localization will lead to improved biopsy outcome, and will be needed as a guide to optimize upcoming local therapies such as intensity modulated radiotherapy, high-intensity focused ultrasound, thermal therapy, cryotherapy and others.

In order to improve non-invasive detection of prostate cancer, its location, heterogeneous extent, grade and stage, currently several new MR techniques are being explored. These include: 1H-MR spectroscopy imaging (MRSI), dynamic contrast-enhanced MR imaging (DCE-MRI), and diffusion weighted imaging (DWI). MRSI provides a substantial improvement of localization compared to T2-weighted MR imaging with accuracies between 74 and 85%. Also, the use of DCE-MRI at 1.5T results in high localization accuracies (88 -89%). The combination of T2-weighted MR imaging with DCE-MRI and MRSI further improves localization accuracy to 91%. This is higher compared to all other non-MR imaging diagnostic tools.

In this study the potential of the following MR methods in addition to anatomical T2-weighted MRI are studied: MRSI, DCE MRI and DWI. The primary objective of this prospective multi-centre study is to prove the diagnostic accuracy of 3T multi-modality MR imaging (high resolution T2-weighted MRI, DCE-MRI, MRSI and DWI techniques) in distinguishing carcinoma from other prostate tissue. The gold standard for distinguishing the tissue types is the analysis of whole-mount sections of the resected prostate by a genitourinary histopathologist.

Study objective

To prove the diagnostic accuracy of 3T multi-modality MR imaging (high resolution T2-weighted MRI, DCE-MRI, MRSI and DWI techniques) in distinguishing carcinoma from other prostate tissue. The gold standard for distinguishing the tissue types is the analysis of whole-mount sections of the resected prostate by a genitourinary histopathologist.

Study design

Prospective multi-centre clinicopathologic study. Two-hundred patients will be included in this study.

Study burden and risks

MR imaging may cause some discomfort, such as feelings of claustrophobia and discomfort due to loud sounds of the MR instrument during the study. Patients are screened for prior claustrophobic symptoms using the same screening form described above to search for metal device and foreign bodies. Earplugs are provided to all patients in order to minimize the discomfort related to the loud noise.

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 diagnosis of adenocarcinoma of the prostate
• Radical prostatectomy and histopathological exam planned

Exclusion criteria

• Patients who are unable to undergo an MR exam, including subjects with contra-indications to MR exams
• Therapy or surgical procedure applied to the prostate or to other organs in vicinity to the prostat

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):	01-06-2010
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	05-10-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL26836.091.09