PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Prostate Cancer Localization With a Multiparametric MR Approach

Trial Acronym

PCa-MAP

URL of the trial

[---]*

Brief Summary in Lay Language

The primary objective of this prospective multi-centre study is to prove the diagnostic accuracy of in vivo 3T multi-modality Magnetic Resonance 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.

Brief Summary in Scientific Language

Goal Proving that multi-parametric MR imaging in a multi-centre setting allows for localizing clinically significant (volume > 0.5cc; Gleason > 6) prostate carcinoma in the prostate.

Objective 1

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:

1. focal areas of low signal intensity on T2-weighted images;

2. 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;

3. the extent and degree of apparent diffusion coefficient reduction on DWI;

4. the extent and degree of perfusion abnormality on DCE-MRI; with the presence or absence of cancer at (reconstructed) whole mount section histopathology.

Objective 2 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.

Organizational Data

- DRKS-ID: **DRKS00004124**
- Date of Registration in DRKS: **2012/10/11**
- Date of Registration in Partner Registry or other Primary Registry: **2010/06/04**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01138527 (ClinicalTrials.gov)**
- Sponsor-ID: **RU PCa-MAP (Radboud University)**

Health condition or Problem studied

- Free text: **Prostate Cancer**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **Other: MRI examination**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***

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Study Type Non-Interventional: **Observational study**

Allocation: **[---]***

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Area under the ROC curve to distinguish between cancer and non-cancer tissue in the prostate; time frame: December 2015

Secondary Outcome

- Area under the ROC curve to separate low aggressive from intermediate and high aggressive prostate cancer; time frame: december 2015

Countries of recruitment

- AT **Austria**
- BE **Belgium**
- CA **Canada**
- DE **Germany**
- NL **Netherlands**
- NO **Norway**
- UK **United Kingdom**
- US **United States**

Locations of Recruitment

- **University Medical Center Mannheim, Heidelberg University, Mannheim**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/06/30**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Biopsy-proven diagnosis of adenocarcinoma of the prostate

- Subject will sign a consent form prior to study entry

- Radical prostatectomy and histopathological exam planned

- The time interval between last biopsy and the MR exam must be at least 4 weeks

- The time interval between MR exam and radical prostatectomy should not exceed 12 weeks

Exclusion criteria

- Subjects who are unable to give valid informed consent

- Subjects who are unwilling or 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 prostate: among the therapies preventing inclusion are any form of radiation therapy, cryo-therapy, thermal-therapy, therapy based on any other medication (including hormonal therapy).

- Patients under hormone deprivation therapy.

Addresses

- **Primary Sponsor**

  Radboud University

  Telephone: **[---]***
  Fax: **[---]***
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- **Contact for Scientific Queries**

  Radiology, Radboud University Nijmegen Medical Centre
  Tom W Scheenen, PhD

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- **Collaborator, Other Address**

  Siemens AG

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- **Collaborator, Other Address**

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Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 6

- Last processed date by ClinicalTrials.gov: 2016/01/14

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.