Trial Description

Title

Multiparametric MRI for active surveillance of Patients with a low-risk Prostate Cancer: A Prospective, Longitudinal, Multicentric, Comparative Study

Trial Acronym

MR ProActive

URL of the trial

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Brief Summary in Lay Language

In this study, patients with low-risk prostate cancer will be highly surveilled in short intervals in order to react properly and fast to tumor changes. Therfore, the both blood samples for PSA determination and tissue samples will be taken regularly. This modus operandi is called active surveillance and is part of clinical routine. In this study, an additional imaging approach will be applied before biopsy, the multiparametric MRI (mpMRI). The study's goal is to develop a new approach for the exact characterization of prostate cancer. It is to clarify, if a non-invasive method such as mpMRI is able to generate exact information for the surveillance of prostate cancer. The current routine's surveillance consists of regularly taken biobsy samples. For the biopsy different approaches are available, such as the transrectal ultrasound guided biopsy (systemic biopsy). In this study, these biopsy methods will be improved as well. Additional to the systemic biopsy, an imaging guided biopsy will be performed in this study depending on the clinical, medical indication. Therefore, the tissue sample will be taken with high accuracy depending on the MRI result.

Brief Summary in Scientific Language

The "active surveilleance" is already part of the strategic management and used in patients with locally restricted low-risk prostate cancer. Therefore, the tumor stage is monitored regularly with surrogate parameter such as PSA or systemic biopsy samples. Thus, therapies with potentially curative intention including high expression of side effects should be deferred till the tumor reaches a stadium (Gleason Score > 6, T>T2a) that requires a therapy. The advantage of this approach is the avoidance of therapy attached side effects in minimal tumor mortality and good quality of life. However, two problems are still remaining that impair the ideal active surveillance by deficient ris stratification: 1. Exaggerated treatment of an indolent disease and 2. the underestimation of an indication, that is not suitable for active surveillance. Furthermore, the avoidance of the invasive transrectal ultrasonic guided biopsy is preferable in favor of a non-invasive imaging approach and if applicable a more precise biopsy method.
The multiparametric MRI (mpMRI) is a well established non-invasive diagnostic approach for the evaluation of the prostate's primary tumor. This approach is partly implemented in Germany and it belongs already to the NICE guidelines in the UK. Further, this approach seems to be suitable for the inital and longitudinal risk stratification in low-risk PCa within the scope of active surveillance.The

principal reason of using MRI in this indication is the validation/correction of a digital rectal examination and systemic biopsies, such as a low-risk result based on a transrectal ultrasonic guided biopsy. The additional morphological and functional information can confirm and correct the estimated volume and the differentiation of the detected tumor. Moreover, additional lesions in the anterior or apical part of the prostate can be detected and confirmed. Thus, the potential role of mpMRI in this setting is the precise, accurate and non-invasive determination of disease progression by grade and volume. Moreover, the MRI morpholgy can be considered as a undependant prognostic factor. The combination of serial mpMRI with the targeted MRI guided biopsy (trageted biopsy) is a alternative approach with more accuracy compared to the conventional systemic biopsy. The number of unnecessarily performed systemic biopsies might be potentially reduced by using the targeted biopsy approach and a higher accuracy of the determination of the disease degree might be achieved as well. In case of a fast PSA increase, the mpMRI including targeted biopsy can be also considered as a very accurate approach compared to the systemic biopsy. The primary goal of the prospective and multicentric study intended is the comparison of mpMRI with targeted MRI-guided biospsy (if applicable) and the systemic biopsy in terms of the progression rate of low-risk to intermediate/high-risk PCa 15 +/-1 month after 1°systemic re-biopsy. Therefore, 217 patients with a histologically proven PCa (Gleason-Score< 6) will be included in the study. Further goals: Collection of up-grade and up-stage rate in inital re-biopsy after 6 months, predictive value of the tumor's MRI morphology (classified according to PI-RADS) regarding staging and progression rate.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013915**
- Date of Registration in DRKS: **2018/01/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **466/2017BO1 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **The treatment and support of the patients within the scope of active surveillance will be performed accordingly to the latest, actual guidelines: regular determination of the PSA-value and systemic biopsies are standard-of-care approaches and will be conducted in patients anyway. Within the scope of the study, a maximum of two additional mpMRI measurements will be performed. If a positive location with tumor suspectedness is detected by MRI imaging a targeted MRI-guided biopsies will be performed.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Grade of conformity of both approaches (mpMRI +/- targeted MRI-guided biopsy versus systemic biopsy) with regards to progression rate to significant prostate cancer (e.g. Gleason Score>7 or T>T2a) after 15+/1 months of active surveillance

Secondary Outcome

carcinoma detection rate of mpMRI (t0,t1)

Rate of up-grading/staging re-biopsies at t0 and t1 with regards to the primary dignosis

Definition of quantitative threshold values (ktrans, ADC for differentiation of low-risk and significant prostate cancer (Gleason>6 or T>T2a)

conformity of histopathological results of systematic biopsy and targeted MRI-guided biopsy

Definition of quantitative threshold values for e.g. ktrans, ADC and texture for the prediction of the tumor progression to significant prostate cancer (e.g. Gleason Score > 6 oder T>T2a).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Abt. Diagnostische & Interventionelle Radiologie und Abteilung für Urologie, Tübingen</style>
- Medical Center **Charité, Inst. für Radiologie und Charité, Klinik für Urologie, Berlin**
- University Medical Center **Inst. für Radiologie und Klinik für Urologie, Düsseldorf**
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Inst. & Poliklinik für Radiologische Diagnostik und Klinik & Poliklinik für Urologie, Dresden</style>
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Inst. für Diagnostische & InterventionelleRadiologie & Neuroradiologie UND Klinik für Urologie , Essen</style>
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Inst. für Diagnostische & InterventionelleRadiologie UND Klinik für Urologie, Frankfurt a.M.</style>
- University Medical Center **Klinik für Radiologie UND Klinik für Urologie, Freiburg im Breisgau**
- University Medical Center **Deutsches KrebsforschungszentrumRadiologie (E010) UND Urologische Klinik, Heidelberg**
- University Medical Center <style fontName='DejaVu Sans' isBold='true'>Klinik & Poliklinik für Diagnostische &Interventionelle Medizin UND Univ.-Klinikum Mainz,Klinik & Poliklinik für Urologie , Mainz</style>
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Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/02/01**
- Target Sample Size: **217**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Age ≥18 years
• histological proven PCa
• Gleason Score ≤6
• Tumor in ≤ 2 biopsy samples/punches
• ≤ 50 % Tumor per punch.
• not yet performedre-biopsy or control-MRI after primary dignosis
• Stages T3/T4 excluded
• Serum PSA ≤10 ng/ml
• written and signed informed consent

Exclusion criteria

• Gleason Score ≥7
• Extra capsular extension
• Tumorstages T3/T4
• previous radiotherapy of the pelvis
• previous prostate surgery
• Impairment of blood coagulation/ anticoagulation
• Contraindications for MRI, e.g.:
- all kind of metal on or within the body, pacemakers, artificial cardiac valves, metal prothesis, implanted magnetic metals (screws, surgical plates), metal splinters, permanent dental braces, acupunctur-needle, insuline pumps, intraport etc., tattoos
- patients with restricted thermal sensor or increased thermal sensitivity
- patients with an auditory disease or an increased auditory sensitivity
- Claustrophobia
- extreme adipositas
- Contraindications for Gadolinium contrast agents (GFR-Rate: <30 ml/min/1,73m²)

Addresses

■ **Primary Sponsor**

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- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

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