PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Focal therapy of prostate cancer using mpMRI/TRUS-guided high intensity focused ultrasound (HIFU) technology: a prospective register study (FOXPRO_REGISTER)

Trial Acronym

FOXPRO_REGISTER

URL of the trial

http://none

Brief Summary in Lay Language

Prospective register study to evaluate if focal therapy of prostate cancer using mpMRI/TRUS-guided HIFU represents a therapy alternative for localized prostate cancer in patients who refuse guideline conform prostate cancer treatment. We hypothesis that a local cancer control can be achieved.

Brief Summary in Scientific Language

Focal therapies for localized prostate cancer are described in recent guidelines to be the therapeutic approach with the most important future potential in treatment. Focal therapy through HIFU focuses conglomeration of ultrasound waves on a specific point in the prostate and leads through overheating to protein denaturation and necrosis. The latest HIFU device for the first time utilizes the fusion of mpMRI and trans-rectal ultrasound(TRUS) imaging. Due to a high negative predictive value for mpMRI, it is used in combination with a mpMRI/TRUS-guided biopsy to decide which areas should not be treated.
The optimized mpMRI/TRUS-HIFU approach has potentially less morbidities than described whole gland treatment options. This mpMRT/TRUS HIFU technology holds great promise to progressively revolutionize the efficacy and safety of PCA treatment in selected patients.

Organizational Data

- DRKS-ID: **DRKS00009021**
- Date of Registration in DRKS: **2015/10/19**
- 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.: **2015-401M-MA-§ 23b MPG , Medizinische Ethik-**

DRKS-ID: **DRKS00009021**
Date of Registration in DRKS: **2015/10/19**
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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
Ethics Approval/Approval of the Ethics Committee: **Approved**
Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg

Secondary IDs

- Universal Trial Number (UTN): **U1111-1172-9491**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **- Focal ablation of prostate cancer lesion or lesions within the prostate using multiparametricMRI/ transrectal-ultrasound(TRUS)-guided HIFU (device: FocalOne®, EDAP TMS GmbH, France) after diagnosis with a 12-core prostate biopsy or targeted biopsy of the prostate using mpMRI imaging**
- 12 months post-therapy control biopsy of prostate using multiparametricMRI/transrectal-ultrasound(TRUS)-fused prostatic biopsy

Characteristics

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

Primary Outcome

Focal ablation of prostate cancer with negative mpMRI/TRUS fused biopsy at 12 mo after treatment*
***in case of contraindications against a MRI: ultrasound-guided only**

Secondary Outcome

Secondary treatment free time
Biochemical treatment failure
Metastatic-free survival
Cancer-specific mortality
Overall mortality
Functional outcome
Clinical validity of mpMRI to analyse the presence of residual or recurrent cancer compared with histopathologic findings using control biopsy*
***if no contraindications against a MRI**
Assessment of safety:
60-day postoperative complications using Clavien-Dingo grading system

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Urologie, Mannheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/09**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- refusion of guideline conform prostate cancer therapy
- serum PSA: PSA ≤ 30 ng/ml
- mpMRT/TRUS bioptic proven prostate cancer:
Clinical stage: localized
- No inclusion into trial FOXPRO or FOXPRO_RAD possible

Exclusion criteria

acute urinary tract infection; lymph node or bone metastasis

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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