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

Trial Description

Title

A Prospective Study to Evaluate MRI Guided Biopsy Compared With Transrectal Ultrasound Guided Biopsy of the Prostate in Men With Increased PSA Values

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The purpose of this study is to determine whether MRI guided prostate biopsy achieves higher
prostate cancer detection rates compared with transrectal ultrasound guided prostate biopsy
in patients with increased PSA values > 4.0 ng/ml.**

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00004036**
- Date of Registration in DRKS: **2012/07/11**
- Date of Registration in Partner Registry or other Primary Registry: **2012/03/01**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01553838 (ClinicalTrials.gov)**
- Sponsor-ID: **002 (Heinrich-Heine University, Duesseldorf)**

Sponsor-ID: **002 (Heinrich-Heine University, Duesseldorf)**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Device: MRI guided prostate biopsy and TRUS guided biopsy**

Characteristics

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

Primary Outcome

- Prostate cancer detection rate; time frame: 3 years

Secondary Outcome

- Number of Participants with Adverse Events as a measure of Safety and Tolerability; time frame: 3 years

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Department of Urology, Duesseldorf**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/01/31**
- Target Sample Size: **248**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

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

Additional Inclusion Criteria

- PSA > 4.0 ng/ml

- written informed consent

- age >18

Exclusion criteria

- patients with prostate cancer

- patients with prior prostate biopsy

- patients with contraindications against MRI or biopsy

Addresses

- **Primary Sponsor**

  Heinrich-Heine University, Duesseldorf

Primary Sponsor

Heinrich-Heine University, Duesseldorf

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

- **Contact for Scientific Queries**

Department of Urology, University of Duesseldorf
Christian Arsov, MD

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

- **Contact for Public Queries**

Department of Urology, University of Duesseldorf
Christian Arsov, MD

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

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 complete**
- Study Closing (LPLV): **2013/10/01**

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.