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

Trial Description

Title

Detection of Micrometastases in Lymph Nodes of Patients With Prostate Cancer

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The purpose of this study is to set up a model for detecting micrometastases in Lymph nodes
of patients with prostate cancer by quantitative polymerase chain reaction and its impact on
progression-free survival.**

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00006418**
- Date of Registration in DRKS: **2014/11/19**
- Date of Registration in Partner Registry or other Primary Registry: **2010/02/27**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01615965 (ClinicalTrials.gov)**
- Sponsor-ID: **2607/09 (Technische Universität München)**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Other: tumor marker detection in lymph nodes**

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): **[---]***

Primary Outcome

- Biochemical recurrence free survival; time frame: 2 years; Influence of molecularbiologic micrometastases in lymph nodes on biochemical recurrence free survival in comparison with patients who have histopathologic macrometastases or no evidence of lymph node metastases

Secondary Outcome

- Frequency of molecular detected lymph node micrometastases according to their topography; time frame: 2 years; Description of the anatomic distribution of molecularbiologic lymph node micrometastases in prostate cancer patients treated with radical prostatectomy and extended lymphadenectomy.
The frequency of molecular detected lymph node micrometastases according to their anatomic distribution at the obturatoric fossa, external iliac, internal iliac and common iliac arteries´ region will be reported.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Urologic Department, Munich**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/02/27**
- Target Sample Size: **160**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- Histologically confirmed prostate cancer

- Locally operable tumor

- Negative bone scan (obligatory if Gleason Score > 7 or PSA > 20ng/ml

- Karnofsky ≥ 80%

- Age 18 - 75 years

- Informed consent in written form

- Sufficient hematologic, coagulatory and renal function

- Compliant patient and geographic precondition for adequate follow-up given

Exclusion criteria

- Manifest secondary tumor

- Organ metastases on CT-scan /MRI or in Histology

- Myocardial infarction or stroke within the last 6 months

- Severe cardiovascular (Grade III - IV according to NYHA), pulmonary (pO2 < 60 mmHg), renal, hepatic oder hematopoetic impairment

- Severe active or chronic infection (z.B. pos. HIV-Antibody-Test, HBs-Ag-detected in Serum and/ or chronic Hepatitis)

- Severe psychiatric disease

- Previous chemotherapy

- Previous pelvine radiotherapy

Addresses

■ **Primary Sponsor**

Technische Universität München

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 continuing**

■ Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial 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: 4
- 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.