Trial Description

Title

Prospective Randomized Study to Compare a Limited versus Extended Pelvine Lymphadenectomy during Prostatectomy - SEAL - AP 55/09

Trial Acronym

SEAL

URL of the trial

[---]*

Brief Summary in Lay Language

**This study is meant to show if the extension of lymphadenectomy during prostatectomy has an influence of outcome of patients. Patients with indication to prostatectomy due to prostate cancer will be included.
Both extensions of lymphadenectomy are used in hospitals as a free choise. This study shell show if one method is more effective than the other.**

Brief Summary in Scientific Language

Influence of different extension of Lymphadenectomy to outcome of patients (PSA-Progress)

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003256**
- Date of Registration in DRKS: **2012/01/20**
- Date of Registration in Partner Registry or other Primary Registry: **2011/08/05**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**

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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **2010220 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

- Primary Registry-ID: **NCT01555086 (clinicaltrials.gov)**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Limited pelvine Lymphadenectomy**
- Arm 2: **Extended pelvine Lymphadenectomy**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

PSA-progresse within 5 years, 3-monthly Follow-up with PSA-measurement in blood

Secondary Outcome

- Comparison of overall survival and morbidity after limited versus extended lymphadenectomy within 5 years after prostatectomy
- Development of standard surgery procedures of the radical prostatectomy and lymphadenectomy as well as histopathological procedures for evaluation of tissues. For surgery therapy a precise definition of lymphnode fields that should be cleared within pelvine lymphadenectomy is very relevant. Also, the implementation of quality criteria like minimum account of lymphnodes to clear and definition of resection frames via additional tissue probes evaluation from resection frame. These standards shell be implemented into UICC-classification then.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **RWTH Aachen, Aachen**
- Medical Center **St. Antonius-Hospital, Gronau**
- Medical Center **Martini-Klinik, Hambrug**
- Medical Center **Klinikum Fulda, Fula**
- Medical Center **Krankenhaus Maria Hilf Krefeld, Krefeld**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/08/16**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Male**

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- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- stamp bioptic secured prostate cancer with intermediate or high risk profile (defined as Gleason-Score 7-10 or PSA > 10 ng/ml)

- locally-operable tumor according to DRU/TRUS

- negative bone scan

- negative CT abdomen / pelvis

- general condition according to Karnofsky >/= 80%

- written consent of the patient

- adequate hematological, renal and coagulation physiological functions

- Patient compliance and geographic proximity to allow adequate follow-up

Exclusion criteria

Manifest secondary malignancy
Secured metastasis by histologically or by imaging
Myocardial infarction or stroke within the last 6 months
Existing major cardiovascular (grade III - IV according to NYHA), pulmonary (pO2 <60 mmHg), renal, hepatic or hematopoietic (eg severe bone marrow aplasia) diseases
Severe active or chronic infections (eg pos. HIV-Ab test, HBs-Ag detection in serum and / or chronic hepatitis)
severe psychiatric disease
prior chemotherapy (allowed is a preoperative antiandrogen therapy ≤ 3 months)
previous pelvic radiotherapy
Patients in a closed institution according to an authority or court decision
People who are in a dependent relationship or working relationship with the sponsor or investigator
simultaneous participation in another clinical trial

Addresses

- **Primary Sponsor**

Univsitätsklinikum Essen
Ms. Dr. Katrin Weidler
Hufelandstr. 55

Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

Arbeitsgemeinschaft Urologische Onkologie (AUO) in der Deutschen Krebsgesellschaft e. V.
Seestr. 11
17252 Schwarz
Germany

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Fax: **039827/9 678**
E-mail: **AUO at MeckEvidence.de**
URL: **www.auo-online.de**

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.