

Trial Description

Title

Salvage lymph node dissection with adjuvant radiotherapy for Choline-PET-CT positive lymph node metastases in patients with nodal recurrence of prostate cancer

Trial Acronym

Salvage lymphadenectomy for nodal prostate cancer recurrence

URL of the trial

[---]*

Brief Summary in Lay Language

Prostate cancer represents the most commonly diagnosed malignant tumor in men and is responsible for 11% of deaths. For tumors requiring treatment, radical removal of the prostate and radiation therapy represents options with curative intent. Despite initial good clinical results, dependent on tumor stage, in about 17-40% after primary therapy biochemical recurrence occurs. Biochemical recurrence is diagnosed by rising of the tumor-marker PSA (prostate specific antigen) in serum. Bone metastases as a cause of prostate cancer relapse is linked to poor prognosis and survival and rules out a possible cure.

However, the question of prognosis and adequate treatment for men with exclusively nodal prostate cancer recurrence is completely unanswered.

The current standard treatment for these patients is hormonal castration and finally chemotherapy. Antihormonal therapy leads to severe side effects and has limited effects due to the development of a hormone refractory tumor stage.

Every form of systemic standard therapy for prostate cancer, like castration and chemotherapy, has no curative properties and invariably leads to a refractory tumor stage with poor prognosis. Alternative established approaches to hormonal therapy for patients with nodal prostate cancer recurrence are not available.

In literature and present studies patients with bone and lymph node metastases had been "historically" summarized to one group. Furthermore it is challenging to diagnose lymph node metastases by conventional imaging (CT, MRI). Nowadays, due to excellent enrichment of radionuclides ¹¹C-choline and ¹⁸F-choline especially in lymph node metastases it is possible to distinguish with high reliability between healthy lymph nodes from affected lymph nodes by Choline-PET-CT.

The aim of this retrospective study is to analysis 52 salvage lymphadenectomies, based on Choline-PET-CT findings, performed in 47 patients with nodal prostate cancer recurrence.

Furthermore, we want to analyze whether a PSA-reduction in terms of curation

can be achieved by surgical removal of lymph node metastases, or whether the therapeutic influence is only temporary. We also will analyze which patients are suitable for such treatment and which factors will influence success or failure.

Brief Summary in Scientific Language

Prostate cancer represents with 29% the most commonly diagnosed malignant tumor in men and is responsible for 11% of deaths.

For tumors requiring treatment, radical removal of the prostate (radical prostatectomy with primary pelvic lymphadenectomy) and radiation therapy represents options with curative intent.

Despite initial good clinical results, dependent on tumor stage, in about 17-40% after primary therapy biochemical recurrence occurs. Biochemical recurrence is diagnosed by rising of the tumor-marker PSA (prostate specific antigen) in serum.

Bone metastases or visceral metastases as a cause of prostate cancer relapse is linked to poor prognosis and survival and rules out a possible cure.

However, the question of prognosis and adequate treatment for men with exclusively nodal prostate cancer recurrence completely unanswered.

The current standard treatment for these patients is hormone deprivation therapy and finally chemotherapy. Antihormonal therapy leads to severe side effects and has limited effects due to the development of a hormone refractory tumor stage.

Every form of systemic standard therapy for prostate cancer, like castration and chemotherapy, has no curative properties, and invariably leads to a refractory tumor stage with poor prognosis. Alternative established approaches to hormonal therapy for patients with nodal prostate cancer recurrence are not available.

In literature and present studies patients with bone and lymph node metastases had been "historically" summarized to one group. Furthermore it is challenging to diagnose lymph node metastases in conventional imaging (CT, MRI). Nowadays, by an excellent enrichment of radionuclides ¹¹C-choline and ¹⁸F-choline especially in lymph node metastases it is possible to distinguish by application of Choline-PET-CT with high reliability between healthy lymph nodes from affected lymph nodes.

The aim of this retrospective study is to analyze 52 salvage lymphadenectomies, based on Choline-PET-CT diagnostics, performed in 47 patients with nodal prostate cancer recurrence.

Furthermore, we want to analyze whether a PSA-reduction in terms of curation can be achieved by surgical removal of lymph node metastases, or whether the therapeutic influence is only temporary. We also will analyze which patients are suitable for such treatment and which factors will influence success or failure.



Organizational Data

- DRKS-ID: **DRKS00003472**
- Date of Registration in DRKS: **2012/05/29**
- 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.: **135/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**
- ICD10: **C77 - Secondary and unspecified malignant neoplasm of lymph nodes**

Interventions/Observational Groups

- Arm 1: **salvage lymph node dissection with adjuvant radiotherapy**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- 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): [---]*

Primary Outcome

PSA-progression free survival

Secondary Outcome

**clinical progression of prostate cancer
tumor specific and overall survival**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Urologische Klinik, Klinik für Strahlenheilkunde, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/01**
- Target Sample Size: **47**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Patients with biochemical relapse after radical prostatectomy or primary radiotherapy, evidence (11C-choline or 18F-fluorethylcholin-PET-CT) for nodal recurrence of PCA , Charlson-Comorbidity-index ≤ 2 , age < 80 years.

Exclusion criteria

Presence of bone or visceral metastases, Charlson-Comorbidity-index > 2 , age > 80 years, presence of untreated local recurrence in prostatic fossa, continuation of anti hormonal therapy

Addresses

■ Primary Sponsor

**Universitätsklinikum Freiburg
Hugstetter Str. 55
79098 Freiburg
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ Contact for Scientific Queries

**Universitätsklinikum Freiburg,
Urologische Klinik
Ms. Dr. med. Cordula Jilg
Hugstetter Strasse 55
79106 Freiburg
Germany**

Telephone: **0761/270-28920**

Fax: **0761/270-28780**

E-mail: **cordula.jilg at uniklinik-freiburg.de**

URL: **http://www.uniklinik-freiburg.de**

■ Contact for Public Queries

**Universitätsklinikum Freiburg,
Urologische Klinik
Ms. Dr. med. Cordula Jilg
Hugstetter Strasse 55
79106 Freiburg
Germany**

Telephone: **0761/270-28920**

Fax: **0761/270-28780**

E-mail: **cordula.jilg at uniklinik-freiburg.de**

URL: **http://www.uniklinik-freiburg.de**

Sources of Monetary or Material Support

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

**Universitätsklinik Freiburg
Abteilung Urologie
Mr. Prof. Dr. Ulrich Wetterauer
Hugstetterstraße 55
79106 Freiburg**

DRKS-ID: **DRKS00003472**

Date of Registration in DRKS: **2012/05/29**

Date of Registration in Partner Registry or other Primary Registry: [---]*



Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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

**Universitätsklinik Freiburg
Abteilung Urologie
Mr. Prof. Dr. Ulrich Wetterauer
Hugstetterstraße 55
79106 Freiburg
Germany**

Telephone: **0761-270-28930**

Fax: **0761-270-28780**

E-mail: **ulrich.wetterauer at uniklinik-freiburg.de**

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/06/30**

Trial Publications, Results and other documents

Please note:

There are additional attributes available concerning this trial. To open an extended view please [click here](#).