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

Trial Description

Title

Evaluation of Socioeconomic Aspects Before and After Primary Radiation Therapy (Percutaneous or Interstitial or Combined Percutaneous and Interstitial) in Patients With Prostate Cancer

Trial Acronym

ECOPRO

URL of the trial

[---]*

Brief Summary in Lay Language

This trial is an interrogation of patients with prostate cancer to evaluate socioeconomic effects of radiotherapy. Patients with percutaneous or interstitial or combined percutaneous and interstitial radiotherapy are included. Beside medical effects and adverse events, it's prospectively needed to extensively inform patients about socioeconomic aspects associated with radiotherapy. The interrogation comprises to collect possible costs and expenditures during and after therapy. Aspects especially concerning post therapy period include additional consultations, individual applied alternative medical care, need for additional medical aids (salves, medicine, bandages) and changes in professional and social situation. It's figured out in what extend costs are absorbed by health insurance coverage. In Germany there is no appropriate trial with respective patient population and respective therapy. Primary endpoint is the evaluation of therapy concerning and follow-up costs as well as changes in social and professional situation. Secondary endpoints are quality of life, adverse events of therapy and the correlation of quality of life, adverse events and economic aspects for the patient and the health insurance coverage.

Brief Summary in Scientific Language

[---]*

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006402**
- Date of Registration in DRKS: **2014/11/28**
- Date of Registration in Partner Registry or other Primary Registry: **2013/04/18**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01849471 (ClinicalTrials.gov)**
- Sponsor-ID: **EP2013 (University of Erlangen-Nürnberg Medical School)**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Other: questionnaires**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **[---]***

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- therapy concerning and follow-up costs associated with changes in social professional situation that is connected with Quality of life; time frame: Participants will be followed for the duration of therapy and for 1 year after the last study treatment; by questionnaires concerning social aspects and quality of life to evaluate connections between these parameters

Secondary Outcome

- adverse events; time frame: Participants will be followed for the duration of therapy and for 1 year after the last study treatment
- correlation of quality of life, adverse events and economic aspects for the patient and the health insurance coverage; time frame: Participants will be followed for the duration of therapy and for 1 year after the last study treatment

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Universitätsklinikum Erlangen, Erlangen**

Recruitment

- Planned/Actual: **[---]***

Planned/Actual: **[---]***

- (Anticipated or Actual) Date of First Enrollment: **2013/04/30**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

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

Additional Inclusion Criteria

- minimal age 18

- low, mediate and high-grade prostate cancer

Exclusion criteria

- tumor recurrence

- surgery as primary therapy

- prior radiotherapy except conventional radiotherapy

- patients with other malignancies

Addresses

- **Primary Sponsor**

  University of Erlangen-Nürnberg Medical School

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

- **Contact for Scientific Queries**

  Strahlenklinik, Universitätsklinikum Erlangen
  Annedore Strnad, MD, MHBA

Contact for Scientific Queries

Strahlenklinik, Universitätsklinikum Erlangen
Annedore Strnad, MD, MHBA

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

- **Contact for Public Queries**

Annedore Strnad, MD, MHBA

Telephone: **++49(0)9131 85**
Fax: **[---]***
E-mail: **annedore.strnad at uk.erlangen.de**
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 ongoing**
- Study Closing (LPLV): **[---]***

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: 3
- 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.