Trial Description

Title

Prostate bed irradiation with alternative radio-oncological approaches

Trial Acronym

PAROS

URL of the trial

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Brief Summary in Lay Language

The PAROS study examines the effects of different radiation techniques on quality of life in the postoperative situation (i.e., after surgery) in three different arms. The standard arm contains a normofractionated irradiation of the prostate, 2 Gy photons are applied on each of the 35 treatment days. The first experimental arm contains a hypofractionated dose irradiation for 19 treatment days with 3 Gy photons each. The 2nd experimental arm hypofractionated irradiation with identical dosage but with protons.

Brief Summary in Scientific Language

As the most common male carcinoma, prostate cancer is a prominent tumor entity in oncology. In addition to definitive radiotherapy, the surgical procedure is considered to be an oncologically equivalent therapeutic alternative for non-metastatic malignancies in the primary setting. However, a subsequent radiotherapy of the prostate bed is often necessary, which takes place as an "adjuvant" treatment immediately after surgery or in the course of a renewed increase in PSA and usually extends over several weeks. For the primary situation (without pre-surgery), several phase III clinical trials have shown that it is possible to shorten radiotherapy by increasing the single dose (called hypofractionation). In the context of two prospective Phase II studies, which were carried out in Heidelberg, it has since been shown that hypofractionation with both photons and protons is safe and feasible even in the postoperative situation.
The current, prospective and randomized PAROS study is now intended to demonstrate a multicentric phase III study as an improvement in the quality of life caused by rectum toxicity (primary endpoint) by the use of protons. The oncological non-inferiority of hypofractionated radiotherapy after surgery is a secondary endpoint.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00015231**
- Date of Registration in DRKS: **2018/09/27**
- 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.: **S-435/2018 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **photon IMRT normofractionated (35 x 2 Gy)**
- Arm 2: **photon IMRT hypofractionated (19 x 3 Gy)**
- Arm 3: **protons hypofractionated (19 x 3 Gy(RBE))**

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: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

The primary endpoint: Hypofractionated Proton radiotherapy improves rectal quality of life (using the bowel symptom subscale of the QLQ PR 25) compared to the two photon arms. This is evaluated on the difference 12 weeks after the beginning of radiotherapy vs. baseline.

Secondary Outcome

• Non-inferiority of the hypofractionated therapy arms (arm 2 + 3) compared to the standard arm (arm 1) in terms of biochemical progression-free survival (bPFS) after 5 years. To determine the biochemical lack of recurrence, PSA determinations are carried out consecutively. Two consecutive rises above the nadir are considered recurrences.

• Overall survival (OS) after 5 years

• Quality of life according to EORTC QLQ-C30 after 2 and after 5 years

• clinical symptoms and toxicity
(including mortality) after NCI CTCAE version 5.0 at 2 (and after 5) years

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Heidelberg, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/09/14**
- Target Sample Size: **897**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- histologically confirmed prostate cancer with classification according to the Gleason score and recent PSA-value

- Indication for the irradiation of the prostate bed (adjuvant / salvage) after prostatectomy

- Karnofsky index ≥ 70%

- Age ≥ 18 years

- Patient information and written consent

- Ability of the patient to consent

Exclusion criteria

- antihormonal therapy

- lymphoid metastasis

- R2

- Stage IV (distant metastases)

- previous radiotherapy in the pelvis

- hip total endoprosthesis

- Simultaneous participation in another clinical trial that could influence the results of one of the studies

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*