Trial Description

Title

Liquid biopsies for personalized cancer therapy of rectal cancer

Trial Acronym

Kolibri

URL of the trial

[---]*

Brief Summary in Lay Language

Colorectal cancer is one of the most commonly diagnosed cancers in Europe. Patients with advanced rectal cancer are being treated with a combined approach, consisting of (I) combined radiochemotherapy (radiotherapy and simultaneous chemotherapy), subsequent surgery and possibly followed by adjuvant (supporting) chemotherapy; or (II) combined neoadjuvant short-term radiotherapy, subsequent surgery and possibly followed by adjuvant chemotherapy. However, patients are responding differentially to the treatment. Many patients are possibly being over-treated, whereas other patients would benefit from an intensified treatment. In order to adjust the treatment to every patient, the biological characteristics of the tumors of the study patients will be analyzed and evaluated together with their treatment response. In addition, blood samples and on facultative basis also urine samples will be taken at regular intervals, in order to identify molecules (so called biomarkers) within these samples, which are associated with (1) therapy response and (2) potential tumor recurrence. In the medium term, these blood- and/or urine-based biomarkers would possibly allow to monitor the treatment response with the help of these non- or low-invasive examinations, may help to intensify or de-intensify the cancer treatment according to the cancer's treatment response and may also allow an early detection of recurrent disease. Some of these biomarkers may also serve in early diagnosis of colorectal carcinoma. In this study, all patients are receiving their anti-cancer therapy according to the current standard.
As part of an amendment, we have included a second arm for patients with short-term radiotherapy alone and have reduced blood sampling time in the follow-up (Ethics Committee of TU Dresden, EK 78022016, 9.10.2017).

Brief Summary in Scientific Language

Colorectal cancer is one of the major malignant tumor entities in Europe. Patients with colorectal cancer are receiving a standardized, multimodal therapy, which implies the interdisciplinary collaboration between the radiooncologists (in terms of rectal cancer), surgeons and oncologists. In this study, biological characteristics of the tumors will be analyzed, which are important for their response to radio-/chemotherapy. To improve therapy monitoring, potential biomarkers such as cell-free RNA, tumor-DNA and tumor-specific exosomes will be isolated from liquid biopsies and their correlation with tumor tissue, clinical parameters and clinical follow-up will be assessed. These investigations should help to reveal the potential of low-invasive liquid-biopsies and their suitability as biomarkers for

personalized cancer therapy.

Organizational Data

- DRKS-ID: **DRKS00009882**
- Date of Registration in DRKS: **2016/03/10**
- 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.: **EK 78022016 , Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden**

Secondary IDs

Health condition or Problem studied

- ICD10: **C20 - Malignant neoplasm of rectum**
- ICD10: **C19 - Malignant neoplasm of rectosigmoid junction**

Interventions/Observational Groups

- Arm 1: **Patients with advanced rectal cancer receiving neoadjuvant chemoradiation. Biomarker analyses of the tumor and blood specimens will be carried out (obligatory); biomarker analyses of urine specimens are being conducted on a facultative basis.**
- Arm 2: **Patients with advanced rectal cancer who receive neoadjuvant short-term radiotherapy. Biomarker analyses of the tumor and blood specimens will be carried out (obligatory); biomarker analyses of urine specimens are being conducted on a facultative basis.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Other**

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

Who is blinded: **[---]***

Control: **Other**

Purpose: **Other**

- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Local recurrence-free survival after 5 years

Secondary Outcome

- disease-free survival after 5 years
- metastases-free survival after 5 years
- overall survival after 5 years
- acute toxicity (clinical examination during treatment)
- late toxicity (clinical examination during follow-up care)
- response to neoadjuvant radiochemotherapy (rectal carcinoma) (arm 1) or on neoadjuvant short-term radiotherapy (arm 2)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Strahlentherapie und Radioonkologie, Klinik und Poliklinik für Viszeral-, Thorax- und Gefäßchirurgie, Medizinische Klinik und Poliklinik I, Dresden**
- Medical Center **Krankenhaus St. Joseph-Stift Dresden, Klinik für Chirurgie, Dresden**

Recruitment

- Planned/Actual: **Actual**
-

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2016/05/12**

- Target Sample Size: **166**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Arm 1
- advanced rectal cancer
- neoadjuvant radiochemotherapy
- cT3 / cT4, cN0 cM0 / 1 or any cN + indep. from T and M Status
- paraffin block from the diagnostic biopsy material and from the surgery preparation available in pathology and for scientific investigation
- imaging examination before surgery available
- surgery report and written histology finding available
- performance status WHO 0-2
- tumor volume and location allow curative radiochemotherapy
- Age ≥ 18 years

Arm 2
- advanced rectal cancer
- neoadjuvant radiochemotherapy
- prescribed dose: 25 Gy à 5 Gy / fraction
- cT3 / cT4, cN0 cM0 / 1 or any cN + indep. from T and M status
- paraffin block from the diagnostic biopsy material and from the surgery preparation available in pathology and for scientific investigation
- imaging examination before surgery available
- surgery report and written histology finding available
- performance status WHO 0-2
- Age ≥ 18 years

Exclusion criteria

- other tumor disease that requires therapy or influences probability of survival of the patient
- tumor independent diseases or conditions which reduce the probability of survival of the patient to < 2 years
- previous irradiation in the pelvic area
- pregnancy
- lack of understanding or lack of cooperation

Addresses

■ **Primary Sponsor**

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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

- Approval of ethics comm. (mandatory for transfer to Studybox) **Kolibri-Ethikvotum**
- trial protocol (mandatory for transfer to Studybox) **Kolibri-Kurzprotokoll**

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.