Trial Description

Title

Optimization of the medical diagnostics and therapy managing in colorectal tumors using F-18-Deoxyglucose (FDG) positron emission tomography (PET) and gene expression data (GenPET Colon-2008).

Trial Acronym

GenPET Colon

URL of the trial

[---]*

Brief Summary in Lay Language

Functional methods like PET/CT provide biological information. FDG is transported into the cells and metabolized (one step) like glucose (sugar), therefore dPET/CT facilitates accurate data about the metabolism. In contrast to the standard use of PET/CT in patients with colorectal carcinomas, we like to perform dynamic measurements. Thus it is possible not only to quantify the metabolism more accurately, but to calculate images of the metabolism. Based on the limited knowledge from the literature, it can be expected that there is a profit for the individual patient. The delineation of tumours is generally improved by parametric imaging. Furthermore, we assume that the tumour classification and the prognostic information about the therapy will be improved by the dPET/CT results. It is planned to perform dPET/CT in 80 patients prior to surgery. The dPET/CT results will be compared to molecular biological data about the tumors as well as the clinical follow up data in order to identify dependencies.

Brief Summary in Scientific Language

PET/CT with FDG is a method for the primary diagnostics, staging, and therapy monitoring of colorectal carcinomas. The value of dynamic, quantitative measurements (dPET/CT) is still not evaluated in detail regarding the individual profit for the patients. Furthermore, the additional information provided by parametric imaging, which enhances the visualisation of tumours with low glucose metabolism, is only be assessed in a small patient collective. Thus, dPET/CT with FDG is likely to provide a progress regarding diagnostics, staging, and follow up as well as the prognostic information. The tracer is planned to be used in 80 patients with colorectal carcinomas prior to surgery. The dPET/CT results will be compared to gene array results as well as clinical follow up data.

Organizational Data

- DRKS-ID: **DRKS00000329**
- Date of Registration in DRKS: **2010/02/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-007/2009 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1113-7528**
- Sponsor-ID: **S-007/2009 (GenPET Colon-2008)**

Health condition or Problem studied

- Free text: **C18.0-C18.9**

Interventions/Observational Groups

- Arm 1: **dynamic PET/CT (dPET/CT) with FDG prior to surgery due to a colorectal carcinoma**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

recurrent free survival

Secondary Outcome

individual survival

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2010/06/01**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Patients with a histologically confirmed primary colorectal carcinoma

Exclusion criteria

rejection of the examination by the patient
diabetes mellitus
acute psychosis and other diseases with limited possibilities to understand the examination
pregnant women
claustrophobic patients

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 planned**
- 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.*