Trial Description

Title

Peptide receptor radionuclide therapy (PRRT) in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NET) - Evaluation of treatment response and hemato- and nephrotoxicity

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

The therapy of neuroendocrine tumors (NET) of the gastrointestinal tracs and pancreas (gastroenteropankreatic NET or GEP-NETs) is usually carried out interdisciplinaryly and depends on the type of tumor and the tumor stage. In early stages, surgery is the therapy of choice. In the case of advanced disease only systemic treatment is usually possible.
Considerable success has been achieved in this case, even after failure of conventional therapies, with peptide receptor radionuclide therapy (PRRT).
In PRRT a radiolabeled peptide binds to the so-called somatostatin receptor, which is expressed on many NET cells. Thus, therapeutic radiation can be brought specifically to the tumor while and non-tumor tissue (having no receptor-expression) is spared.

PRRT has been used since the 90s as a form of tumor specific radiation therapy in the treatment of metastatic or unresectable NET.
By PRRT, further tumor growth is prevented in 40-50% of cases, and a tumor regression is achieved in 30% of cases. The main side effect of PRRT is the radiation exposure of the kidneys and bone marrow and side effects often observed in e.g. chemotherapy such as e.g. nausea and vomiting, are rare.
The response to treatment is monitored by means of so-called tumor markers in the blood and by using imaging modalities.
The tolerability of the therapy (usually 3-5 cycles) is controlled through regular blood counts and determinations of kidney parameters.

Brief Summary in Scientific Language

PRRT is an established systemic therapy for neuroendocrine tumors. The aim of this retrospective study is to capture the observed kidney function or blood disorders correlated to the applied activities and determined organ doses.
Secondary endpoint is the assessment of treatment response.

Organizational Data

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DRKS-ID: **DRKS00008976**

- Date of Registration in DRKS: **2015/08/20**
- 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.: **538/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Gastroenteropancreatic neuroendocrine Tumors.**
- ICD10: **C15-C26 - Malignant neoplasms of digestive organs**

Interventions/Observational Groups

- Arm 1: **Retrospective assessment of hemato- and nephrotoxicity as well as response to therapy in patients with gastroenteropancreatic neuroendocrine tumors (GEP-NET) receiveing peptide receptor radionuclide therapy (PRRT)retrospective evaluation of therapy data**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- 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): **N/A**

Primary Outcome

Determination of significant factors influencing nephro- and hematotoxicity of

PRRT in patients with gastroenteropancreatic neuroendocrine tumors.

Secondary Outcome

Assessment of clinical response to PRRT in patients with gastroenteropancreaticneuroendocrine tumors .

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Nuklearmedizin, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/08/19**
- Target Sample Size: **111**
- 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 suffering from gastroenteropancreatic neuroendocrine tumors treated by PRRT at the Department of Nuclear Medicine since 2009 will be selected.

Exclusion criteria

Patients who received less than 3 cycles of PRRT or patients with incomplete data sets.

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 complete, follow-up complete**
- Study Closing (LPLV): **2017/02/01**

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.*