PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Analysis of renal function during angiostatic therapy with the COX-II inhibitor rofecoxib, in combination with pioglitazone, and trofosfamide or capecitabine in patients with metastatic / advanced cancer.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**Tumor growth is rendered possible by cell division and formation of new blood vessels, mediated in part by prostaglandins ? known as a messenger of inflammation.
Rofecoxib inhibits the formation of prostaglandins and was in this study part of a (combined) tumorsuppressive regimen.
Rofecoxib was well tolerated in this regimen, but withdrawn from the market because of an increased risk of myocardial infarction in the general population.
We analysed renal function during therapy with Rofecoxib in a prospective trial of antiangiogenic / antiinflammatory therapy in patients with advanced cancer.**

Brief Summary in Scientific Language

Cyclooxygenases (both isoforms, COX-I and COX-II) oxidize arachidonic acid to prostaglandin H2, which is converted by different synthases to prostaglandin-E2, -D2, -I2, -F2alpha, and thromboxane A2. These different prostaglandins inhibit apoptosis and promote cell division, metastasis and angiogenesis leading to increased tumor growth. An antiangiogenic / antiinflammatory therapy with COX-II inhibitors and pioglitazone combined with metronomic low-dose chemotherapy with either capecitabine or trofosfamide seems to be well tolerated and promising in patients with advanced carcinomas. COX-II inhibitors have been shown to have less gastrointestinal side effects since they merely block COX-I which catalyzes the production of cytoprotective gastrointestinal prostaglandins. Rofecoxib however was associated with an increased risk of myocardial infarction and thus withdrawn from the market. In a (combined) tumorsuppressive regimen, rofecoxib was generally well tolerated. Since COX-II inhibitors are known to elicit renal side effects to a similar extent than conventional non-steroidal antiinflammatory drugs, the detailed analysis of renal function in a prospective trial of antiangiogenic / antiinflammatory therapy in advanced cancer seemed to be of interest.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000119**
- Date of Registration in DRKS: **2009/06/22**
- 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.: **00/149 , Ethikkommission an der Universität Regensburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C80 - Malignant neoplasm without specification of site**

Interventions/Observational Groups

- Arm 1: **Therapy with 25mg rofecoxib per day, 45mg pioglitazone per day and 1,0g capecitabine bid per os**
- Arm 2: **Therapy with 25mg rofecoxib per day, 45mg pioglitazone per day and 50mg trofosfamide per os**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Single arm study**

Blinding: **Open (masking not used)**

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

- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Primary Outcome / Outcome Measures (of the present secondary analysis):Assessment of renal function during and after end of treatment. Serum creatinine concentrations were measured before treatment and monthly during the treatment phase up to 6 months after end of treatment. Glomerular filtration rate was estimated using the method of Cockcroft and Gault.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2000/07/26**
- Target Sample Size: **87**
- 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 either gastrointestinal cancer, including pancreatic, and gall bladder cancer or urological cancer (group A) or metastatic melanoma, sarcoma, pulmonary and gynecological carcinoma or hematological malignancy (group B) were included in the. Additional eligibility criteria included: adequate baseline organ function as evidenced by a serum creatinine concentration at or below 1.8mg/dl, GOT, GPT and GGT below 1.25 times the normal concentration, white blood cell count over 2.0 cells per nL and a platelet count over 100000 cells per µL. Written informed consent had to be obtained before inclusion in the study.

Exclusion criteria

Patients with significant comorbidity including acute infections, inadequately controlled diabetes mellitus, congestive heart failure, angina pectoris and cardiac arrhythmia requiring medical therapy were excluded from the study.

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2005/10/04**

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.*