DRKS-ID: **DRKS00000242**
Date of Registration in DRKS: **2010/03/04**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

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

Trial Description

Title

CONKO-006:Additive therapy in R1-resected pancreatic cancer with gemcitabine plus sorafenib vs. Gemcitabine plus placebo over 12 months - a double blind, placebo-controlled Phase IIb trial

Trial Acronym

CONKO-006

URL of the trial

http://www.tumorcenter.de

Brief Summary in Lay Language

Patients with pancreatic cancer have a hig risk of relaps of the disease even after a well performed operation. This is especially true for those patients were it was not possible to keep a safety margin to the healthy tissue (so called R1-resection). A chemotherapy with Gemcitabine is actually the standard of care after an operation of pancreatic cancer. In our study CONKO-006 we will try to improve the prognosis of the patients with R-1 resecion by intensifying this adjuvant therapy. The duration of treatment will be 12 months (instead of 6 months) and to the chemotherapy of Gemcitabine a new oral medicament will be added that may influence the vascular feeding of tumour cells.

Brief Summary in Scientific Language

CONKO-006 is a randomized, double-blind placebo-controlled multi-center phase IIb study in patients with R1-resection of pancreatic cancer with two treatment groups. The aim of the study is to demonstrate the usefulness of the additional treatment with the multikinase-inhibitor Sorafebine in combination with the standard therapy of gemcitabine and the efficacity of a prolongation of adjuvant therapy from 6 to 12 months. The antitumoral effect of Sorafenibe is due to the inhibition of tumor proliferation (by inhibiton of raf-kinases and the Raf/MEK-ERK-pathway) and of the tumor specific angiogenesis (by inhibition of VEGF, EGF and PDGF-receptors). Primary endpoint of the study is to compare disease free survival rate 18 months after start of treatment in both treatment groups following potentially curative surgery. A prolongation of disease free survival after 18 months from 42% to 60%, assuming an exponential survival curve, means a prolongation of the median progression free survival from 14,4 to 24,4 months. This calculations are based on the datas of the CONKO-001-study. In this trial the disease free survival for the subgroup of patients after R1-resection was improved from 5,5 months to 15,8 months by a 6 months adjuvant therapy with gemcitabine1. For a few of patients with pancreatic cancer, definitive curation seems possible by adjuvant therapy.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000242**
- Date of Registration in DRKS: **2010/03/04**
- 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.: **ZS EK 11 487/07 , Ethik-Kommission des Landes Berlin**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1114-0963**
- EudraCT-No.
  (for studies acc. to Drug Law): **2007-000718-35**
- BfArM-No.: **4033485**

Health condition or Problem studied

- ICD10: **C25 - Malignant neoplasm of pancreas**

Interventions/Observational Groups

- Arm 1: **Arm A:**
  Sorafenib 400 mg twice daily p.o. plus Gecitabine 1000 mg/ m² day 1, 8, 15 repetition day 29
  Duration: 12 Month
- Arm 2: **Arm B:**
  Placebo twice daily plus Gemcitabine 1000 mg/m² day 1, 8, 15 repetition day 29
  Duration: 12 Month

Characteristics

- Study Type: **Interventional**

Study Type: **Interventional**

- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IIb**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Relaps-free survival

Secondary Outcome

Overall survival
Safety and tolerability
Evaluation of prognostic factors

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/02/08**
- Target Sample Size: **127**
- 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

Histological confirmed diagnosis of an adenocarcinoma of the pancreas, Standardised surgery for tumor resection, e. g. partial pancreatoduodenectomy (Kausch-Whipple), pylorus-sparing partial pancreatoduodenectomy (PPPD), pancreas leftresection or total pancreatectomy, Result of resection: R1, No previous neoadjuvant therapy (chemotherapy or radiation), Performance-Status according to Karnofsky-Scale > 60 %, Patient compliance and geographical situation allowing an adequate follow up, especially the willingness to visit the same center regulary for at least 2 years after surgery, Sufficient bone marrow capacity: WBC > 3.5 /nl, platelets > 100 /nl, haemoglobin > 8 g/dl, Written informed consent of the patient prioral any precedure in connection with the study, Male and female patients with an age of at least 18 years, Initiation of the adjuvant therapy as soon as possible postoperative. Soonest 4 weeks after resection but not before completion of the wound healing, but at latest in between 8 weeks after resection.

Exclusion criteria

Seriouses systemic disease (with life expectance < 6 months) according to estimation of the investigator, active infection > Grad 2 NCI-CTCAE v3.0, Known HIV infection, Serious systemic disease: Uncontrolled hypertension, ingestive heart failure NYHA III - IV, symptomatic coronary heart disease, uncontrolled cardial arrhythmia > grade II, peripher arterial disease > stage IIb, International Normalized Ratio (INR) > 1.5, prolongation of the activated partial prothrombin time (aPTT) > 1.5 x UNL (upper normal limit), transaminases > 3x UNL, Postoperative measurable tumorlesion, Pregnant or breast-feeding women. Women of child-bearing potential must have an negative pregnancy test performed 7 days prior to start of the treatment, Sexually active males or females with child-bearing potential unwilling to practice sufficient contraception during the study and for 3 months after end of the study medication., Known allergical reactions against the study drugs or the substances included therein, Patients undergoing dialysis, Interstitial pneumonia or symptomatic fibrosis of the lung, Need of immunosuppressive therapy (e. g. transplantation), Severe non-healing wounds, ulcers or bone fracturs, Participation in another experimental clinical trial within 4 weeks prior to entry into the study, Previous or ongoing narcotic drug, medication- or alcohol abuse, Patients which are not able to take in oral drugs, need parenteral nutrition,are known to have an insufficient gastrointestinal resorption or suffer from acute stomac ulcer, Other primary malignancy in the patient's history (except for successfully treated basalioma or carcinoma in situ of the cervix uteri), patients ordered to be hospitalized by legal decision

Addresses

- **Primary Sponsor**

  Charité-Universitätsmedizin Berlin

Primary Sponsor

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Germany

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Bayer Vital GmbH
Kaiser-Wilhelm-Allee
51368 Leverkusen
Germany

Commercial (pharmaceutical industry, medical engineering industry, etc.)

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51368 Leverkusen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bayervital.de**

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*