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

Trial Description

Title

CONKO-005:Adjuvant Therapy in R0-resected Pancreatic Cancer Patients with Gemcitabine plus Erlotinib vs. Gemcitabine over 24 Weeks - a Prospective, Randomized Phase III Study

Trial Acronym

CONKO-005

URL of the trial

http://www.tumorcenter.de

Brief Summary in Lay Language

Pancreatic cancer is a particularly aggressive tumor with a poor prognosis and surgical resection is the only approach with the possibility of curation. For women it is the 4th and for men the 5th cause of tumor-related death. In addition, there is a recurrence rate of approximately 80% within 5 years. In case of a resectable tumor the 5-year survival rates vary in between 15 - 25% and depend on the result of the resection.
Recent findings from our study group (Oettle 2007) showed that those patients who received postoperative chemotherapy with the gemcitabine had a significantly lower risk of recurrence than those without adjuvant chemotherapy. Even patients with complete (R0) resection have a poor median survival of approximately 18 months.
The CONKO-005 trial will straightly target these R0-resected patients.
It has been repeatedly shown that up to 90% of pancreatic cancers overexpress EGFR.
For this reason the inhibition of EGFR with "small molecules " like erlotinib might be o special interest. CONKO 005 trial evaluates the combination of gemcitabin and the selective EGFR-tyrosine kinase inhibitor erlotinib in the adjuvant setting. It might help to find out if this treatment is able to further reduce the risk of tumor recurrence by destroying intraoperative remaine or disseminated tumor cells.

Brief Summary in Scientific Language

Erlotinib is an inhibitor of tyrosine kinase epidermal growth factor receptor (EGFR, HER-1).
HER1/EGFR is expressed on the surface of normal cells but also by tumor cells. The anti-tumor activity of erlotinib is based on the inhibition of intracellular tyrosine kinase region of HER1, thus preventing the intercellular signal transduction.
In preclinical models, inhibition of HER1 / EGFR tyrosinkinase effects the arrest of growth and / or death of the cell.
Preclinical data show an additive effect with cytotoxic drugs such as cisplatin,

doxorubicin, or paclitaxel.
In these combination studies no side effects were shown.
For erlotinib are also data available from several phase I, II and III trials. Since January 2007 erlotinib has been admitted to a dose of 100 mg / day p.o. in combination with gemcitabine in the first-line therapy of metastatic pancreatic cancer in Europe .
The admission is based on data from a randomized phase III trail with 569 patients, which had demonstrated a significant benefit in overall survival with this combination compared to gemcitabine alone (p= 0.038).
Futhermore in this study the combination of erlotinib and gemcitabine was well tolerated (Moore et al. 2007).

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000247**
- 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 11 521/07 , Ethik-Kommission des Landes Berlin**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1114-0833**
- EudraCT-No.
  (for studies acc. to Drug Law): **2007-003813-15**
- BfArM-No.: **4033532**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Arm A:**
  Erlotinib 100 mg p.o. daily plus Gemcitabin 1000 mg/m² i.v. day 1, 8, 15. repetition day 29
  Duration: 6 cycles (24 weeks)
- Arm 2: **Arm B:**
  Gemcitabin 1000 mg/m² i.v. day 1, 8, 15. repetition day 29

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Relaps-free survival (RFS)

Secondary Outcome

Overall survival, Toxicity

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/04/15**
-

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2008/04/15**

Target Sample Size: **450**

- 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.
Result of resection: R0, 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 × 109 /l, platelets > 100 x 109/l, 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 2 weeks after resection but not before completion of the wound healing 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)

Addresses

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Sources of Monetary or Material Support

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

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Emil-Barell-Strasse 1/ Postfach 1270
79630 Grenzach-Wyhlen
Germany

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