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Targeted therapy in patients with advanced pancreatic cancer

Submission date 11/03/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/05/2008	**Overall study status** Completed	
Last Edited 30/05/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UKF000577

Study information

Scientific Title

A prospective, non-randomised phase II study of trastuzumab and capecitabine in patients with HER2 expressing advanced pancreatic cancer

Study objectives
Pancreatic cancer is the fourth most common cause of cancer related death in Western countries. Advantages in surgical techniques, radiation and chemotherapy had almost no impact on the long term survival of affected patients. Therefore, the need for better treatment strategies is urgent. HER2, a receptor tyrosin kinase of the epidermal growth factor receptor (EGFR) family, involved in signal transduction pathways leading to cell growth and differentiation is overexpressed in a number of cancers, including breast and pancreatic cancer. While in breast cancer HER2 has already been successfully used as a treatment target, there are no studies thus far evaluating the effects of inhibiting HER2 tyrosine kinases in patients with pancreatic cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the University of Freiburg, Germany on the 19th April 2004.

Study design
Prospective, open, one-armed multicentric phase II trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Advanced pancreatic cancer (stage IVb)

Interventions
The trastuzumab loading dose of 4 mg/kg body weight will be given on day one over 90 minutes. For maintenance therapy a weekly dose of 2 mg/kg body weight over 30 minutes will be infused until tumour progression takes place. Patients will be monitored closely for six hours during the first dose of trastuzumab and for two hours after the following rastuzumab infusions to rule out adverse reactions.

Capecitabine will be applied orally twice daily at a dose of 1250 mg/m^2 on day 1 - 14 followed by a break of seven days. The three weeks cycles will be repeated until tumour progression or until a grade three to four toxicity occurs.

Planned duration of treatment 12 weeks or until disease progression. In the case of stable disease treatment is continued until progression. Follow up is performed until death.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Trastuzumab, rastuzumab, capecitabine

Primary outcome measure
Progression free survival after 12 weeks.

Secondary outcome measures
1. Progression free survival time
2. Overall survival
3. Time until remission (partial or complete)
4. Duration of remission
5. Rate of 'clinical benefit response' after 12 weeks
6. Quality of life before treatment and after two cycles of chemotherapy

Additional secondary trial endpoints:
7. Toxicity analysis
8. The rate of adverse events
9. The relationship between progression free survival and CA19-9 plasma levels
10. The relation between HER2/neu overexpression and progression free survival

Overall study start date
01/06/2004

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Written informed consent
2. Aged 18 years or older, either sex
3. Histological verified pancreatic cancer in stage IVb (T1-4N0M1)
4. Staging and CA19-9 serum level not older than four weeks
5. Histological verified over-expression of HER2/neu (immunological score 3+ or 2+ with verification by fluorescent in situ hybridisation [FISH])
6. At least one measurable lesion (greater than or equal to 2 cm in conventional computed tomography [CT] scan or greater than or equal to 1 cm in spiral CT scans)

7. No prior chemotherapy
8. No prior radiotherapy
9. Performace-status 0 - 2 according to World Health Organization [WHO]/Eastern Cooperative Oncology Group [ECOG] or greater than or equal to 60 points on the Karnofsky scale
10. Life expectancy of at least three months
11. Left ventricular excretion fraction greater than 50%
12. Appropriate renal, liver and haematopoetic function defined by:
12.1. Neutrophils greater than or equal to 1.5 x 10^9/l
12.2. Haemoglobin greater than or equal to 80 g/l
12.3. Platelets greater than or equal to 100 x 10^9/l
12.4. Total bilirubin less than 3 x normal
12.5. Creatinine clearance greater than or equal to 30 ml/min (Cockroft Gault)
12.6. Transaminases either less than 2.5 x normal, or less than 5 x normal in case of liver metastasis
13. Possibility of long-term follow up
14. Negative pregnancy testing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
37

Key exclusion criteria
1. Possible surgical resection and/or radiotherapy with curative potential
2. Dihydropyrimidine-dehydrogenase deficiency
3. Gastrointestinal obstruction
4. A known secondary neoplasm except a curative treatable basalioma of the skin or carcinoma in situ of the cervix uteri
5. A known hypersensitivity against any of the applied substances
6. Clinically relevant disorder of the cardiovascular system or other organs or a severe systemic disease that compromises the study protocol or the interpretation of the data
7. Clinically manifest pulmonary disorder
8. Prior polyneuropathy
9. A concomitant treatment with the virustatic agents sorivudin or its analogues
10. Pregnancy, breast feeding or absence of appropriate contraceptive measures
11. Psychiatric disorders, drug abuse or other disorders, that compromise the informed consent
12. Concomitant participation in other clinical trials or participation within the last four weeks
13. Any other disorder or treatment that poses a risk to the patient or is incompatible with the aims of this study

Date of first enrolment

01/06/2004

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Municipal Hospital Esslingen
Esslingen
Germany
73730

Sponsor information

Organisation
Roche Pharma AG (Germany)

Sponsor details
Emil-Barell-Str. 1
Grenzach-Wyhlen
Germany
79639

Sponsor type
Industry

Website
http://www.roche.de

ROR
https://ror.org/00sh68184

Funder(s)

Funder type
Industry

Funder Name

Roche Pharma AG (Germany) - providing chemotherapeutic agents

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration