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A multinational, multicenter, open-label, controlled, randomised, parallel group study to evaluate the efficacy and safety of EMD 121974 and gemcitabine or gemcitabine alone in patients with advanced, unresectable pancreatic cancer

Submission date	Recruitment status	[_] Prospectively registered
23/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/10/2009	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Helmut Friess

Contact details
Abteilung fur Allgemeine
Viszerale-und Unfallchirurgie
Universitat Heidelberg
Im Neuenheimer Feld 110
Heidelberg
Germany
69120

Additional identifiers

Protocol serial number
EMD 121974-004

Study information

Scientific Title

Study objectives
Primary:
1. To investigate the effects of treatment with EMD 121974 and gemcitabine compared to gemcitabine alone on the overall survival in patients with advanced, unresectable pancreatic cancer

Secondary:
1. To investigate the response rates including stable disease
2. To determine the best of all response rates
3. To determine the time to disease progression
4. To assess the safety and tolerability
5. To assess the quality of life
6. To determine the performance status
7. To investigate the biological response (tumor marker levels, and angiogenic growth factor levels)
8. To evaluate the population pharmacokinetic parameters for EMD 121974 as well as gemcitabine and to determine plasma concentration-effect relationships for EMD 121974 with adverse events, primary efficacy parameters, and demographic data

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Institutional boards of the participating centers

Primary study design
Interventional

Study design
Open label, controlled, randomized

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unresectable pancreatic cancer

Interventions
EMD 121974 and gemcitabine versus gemcitabine alone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gemcitabine, EMD 121974

Primary outcome(s)
Overall survival

Key secondary outcome(s)
1. Response
2. Progression
3. Safety
4. Quality of Life
5. Biomarkers

Completion date
07/08/2001

Eligibility

Key inclusion criteria
1. The patient must have provided written informed consent prior to any study-related procedure
2. The patient must be at least 18 years of age
3. The patient must be male or female without childbearing potential (i.e. post-menopausal or sterile)
4. The patient must suffer from histologically confirmed advanced unresectable pancreatic cancer with or without metastases
5. The patient must have at least one bidimensionally measurable or evaluable lesion
6. The life expectancy of the patient must be at least 12 weeks
7. The patient must have a Karnofsky performance score of = 70%
8. Outpatients as well as inpatients can be selected for this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. In the investigators opinion, if the patient is not able to comply with the protocol regulations
2. The patient is a pregnant or lactating female. Females with childbearing potential are

generally excluded from the study.
3. The patient has received chemotherapy, and/or major surgery related to the pancreatic cancer prior to study entry. Palliative surgeries (e.g. for the placement of stents) or explorative laparotomies do not fall into this category.
4. The patient has received prior antiangiogenic therapy
5. The patients laboratory parameters lie within the following ranges: pre-treatment granulocytes <1500 /ml, haemoglobin <9 g/dl, platelet count <100,000 /ml, pre-treatment bilirubin >3 times the upper limit of normal, pre-treatment creatinine >2 times the upper limit of normal
6. The patients liver transaminases lie within the following ranges: serum glutamic-oxaloacetic transaminase (SGOT) (aspartate aminotransferase [AST]) or serum glutamic pyruvic transaminase (SGPT) (alanine aminotransferase [ALT]) >5 times the upper limit of normal
7. The patient has had a second primary malignancy within the past five years except carcinoma in situ of the cervix or adequately treated basal cell carcinoma of the skin
8. The patient has a history of brain metastases. In case of suspected brain metastases, a computer tomography (CT) scan of the skull will be performed. This is not mandatory in asymptomatic patients.
9. The patient has had a major surgery within four weeks of study entry
10. The patient has a history of cerebrovascular accident (CVA) or transient ischemic attack (TIA)
11. The patient has had bypass surgery within six months of study entry, or has clinically significant cardiac or cardiovascular abnormalities (New York Heart Association [NYHA] III/IV) or unstable angina or arrhythmias (Lown class IV) requiring treatment
12. The patient has abnormal clotting disorders as defined by international normalized ratio (INR) >1.5, prothrombin time >18 seconds or activated partial thromboplastin time (APTT) >60 seconds, or patients on anticoagulant therapies. Migratory thrombophlebitis does not fall into this category.
13. The patient is suffering from severe diabetic angiopathy due to a long history of diabetes mellitus
14. The patient has had gastric or duodenal ulcers within six months of study entry, or is at risk of gastrointestinal ulceration due to a high consumption of non-steroidal anti-inflammatory drugs (NSAIDs)
15. The patient has a known active infection with Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV)
16. The patient is suffering from serious uncontrolled infections
17. The patient has a history of allergies against penicillin
18. The patient has a legal incapacity or a limited legal capacity
19. The patient is known for drug abuse or extensive chronic use of alcohol
20. The patient takes or is likely to need prohibited concomitant medication
21. The patient has participated in another clinical study within 30 days of study entry
22. Fertile men not willing to use contraception

Date of first enrolment
15/10/1999

Date of final enrolment
07/08/2001

Locations

Countries of recruitment
Germany

Study participating centre
Abteilung fur Allgemeine
Heidelberg
Germany
69120

Sponsor information

Organisation
Merck KGaA (Germany)

ROR
https://ror.org/04b2dty93

Funder(s)

Funder type
Industry

Funder Name
Merck KGaA (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/12/2006		Yes	No