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Randomized phase II Trial of combined chemoradiation with Epidermal Growth Factor Receptor (EGFR) antagonist Cetuximab versus combined chemoradiation with EGFR antagonist Cetuximab and sequential Cetuximab for patients with locally advanced pancreatic adenocarcinoma

Submission date
11/05/2005

Recruitment status
No longer recruiting

Registration date
13/06/2005

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Randomized phase II Trial of combined chemoradiation with Epidermal Growth Factor Receptor (EGFR) antagonist Cetuximab versus combined chemoradiation with EGFR antagonist Cetuximab and sequential Cetuximab for patients with locally advanced pancreatic adenocarcinoma

Acronym
PARC - Pancreatic Cancer Treatment with Radiotherapy and Cetuximab

Study objectives
Evaluation of EGFR targeting therapy with cetuximab in combination with radiotherapy and chemotherapy for locally advanced pancreatic cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information provided at time of registration.

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pancreatic adenocarcinoma

Interventions
Two arm phase I/II study:
Arm A: radiotherapy and concurrent gemcitabine and EGFR antagonist cetuximab with sequential gemcitabine
Arm B: radiotherapy and concurrent gemcitabine and EGFR antagonist cetuximab with sequential gemcitabine and EGFR antagonist cetuximab

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Cetuximab

Primary outcome(s)
Safety, feasibility and side effects of the combination therapy of chemoradiation and cetuximab

Key secondary outcome(s))
1. Response
2. Time to progress
3. Operability after treatment
4. Time to treatment failure

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Patients with locally advanced primary inoperable pancreatic cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Active infection
2. Liver function impairment
3. Pregnancy
4. Breast feeding
5. Metastatic disease
6. Elevated serum calcium level
7. Other severe systemic disease
8. Second malignancy (except carcinoma in situ of the cervix uteri, basal cell carcinoma of the skin after adequate oncologic treatment)
9. Any other experimental treatment four weeks before study inclusion
10. Known positive HACA (Human Anti-Chimeric Antibody)
11. Known allergy against extrinsical proteins

12. Previous antibody therapy
13. Allergy against intravenous (iv) contrast agent (for Computed Tomography [CT]-scans)
14. Previous chemo- and/or radiation treatment or EGFR-inhibitor therapy for pancreatic cancer

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Im Neuenheimer Feld 400
Heidelberg
Germany
69120

Sponsor information

Organisation
University of Heidelberg (Germany)

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Industry

Funder Name
Merck KGaA, Darmstadt (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?
Protocol article	Study protocol	11/10/2005		Yes	No