# 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

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# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

#### **IRAS** number

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

#### Participant information sheet

## 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 measure

Safety, feasibility and side effects of the combination therapy of chemoradiation and cetuximab

#### Secondary outcome measures

- 1. Response
- 2. Time to progress
- 3. Operability after treatment
- 4. Time to treatment failure

#### Overall study start date

01/01/2005

## Completion date

31/12/2007

# **Eligibility**

#### Key inclusion criteria

Patients with locally advanced primary inoperable pancreatic cancer

# Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

# Target number of participants

66

#### 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)

## Sponsor details

University Hospital Im Neuenheimer Feld 400 Heidelberg Germany 69120 +49 6221 568201 robert\_krempien@med.uni-heidelberg.de

#### Sponsor type

University/education

#### **ROR**

https://ror.org/038t36y30

# Funder(s)

## Funder type

Industry

#### Funder Name

Merck KGaA, Darmstadt (Germany)

# **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

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Study protocol	11/10/2005		Yes	No