

Phase I-/II-study of Hyperfractionated-Accelerated Radiation Therapy plus Cetuximab plus Cisplatin chemotherapy in locally advanced inoperable squamous cell cancers of head and neck

Submission date 13/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/06/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number
Final 01/15.02.05

Study information

Scientific Title

Acronym

HART-CIS-CET

Study objectives

An improvement of loco-regional disease control by addition of cetuximab (CET) to hyperfractionated-accelerated radiation therapy (HART) and cisplatin (CIS) is expected.

As of 01/06/2009 this record has been updated. All updates can be found in the relevant fields under the above update date. At this time, the anticipated end date of this trial was extended from 31/12/2007 to 31/12/2012, and the initial target number of participants was 67.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics commission of the Medical Faculty of the Martin-Luther-University Halle-Wittenberg gave approval on the 10th June 2005.

Primary study design

Interventional

Study design

Open-label, non-randomised phase I/II study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Squamous cell carcinoma (SCC)

Interventions

Phase I:

1. HART: 30/2 Gy once daily, then twice daily 1/4 Gy to a total dose of 70/6 Gy
2. Chemotherapy: cisplatin - escalating doses (20, 30, 35, 40 mg/sqm), once weekly (typically on Monday), week one to six intravenous (iv) over a one hour infusion on days 1, 8, 15, 22, 29, 36
3. Antibody: cetuximab - loading dose 400 mg/sqm iv over a 120-min infusion on day 7 followed by subsequent weekly doses of 250 mg/sqm weeks one to six iv over a one hour infusion on days 1, 8, 15, 22, 29, 36

Phase II:

1. HART: see phase I
2. Chemotherapy: cisplatin at the recommended dose level defined in phase I
3. Antibody: see phase I

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

Cetuximab, cisplatin

Primary outcome(s)

Phase I:

Definition of maximum tolerated dose (MTD) of cisplatin in HART-CIS-CET

Phase II:

Determination of the two year progression-free survival (PFS)

Key secondary outcome(s)

Phase I:

1. Evaluation of toxicity (according to Common Terminology Criteria for Adverse Events (CTCAE) version 3.0)
2. Determination of objective tumour response rate (ORR) (according to Response Evaluation Criteria In Solid Tumors [RECIST])
3. Determination of one, two and five year PFS, loco-regional progression-free survival (LPFS) and overall survival (OS)

Phase II:

1. Determination of one and five year-PFS
2. Determination of one, two and five year LPFS and OS
3. Determination of ORR (according to RECIST)
4. Evaluation of toxicity (according to CTCAE version 3.0)

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Patients with histologically confirmed unresectable squamous cell carcinoma (SCC) of the oral cavity (no lip), oropharynx, hypopharynx or larynx (stage III/IVa or b)
2. Unidimensionally measurable lesion
3. Signed informed consent
4. Karnofsky Performance Status more than or equal to 70%
5. Aged between 18 and 70 years
6. Curative treatment intent
7. Negative serum or urine pregnancy test (women of childbearing potential)
8. Adequate bone marrow, hepatic and renal function

All patients should have a dental examination and appropriate, dental therapy if required prior to the beginning of radiotherapy. A percutaneous gastrostomy (PEG) is required.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Unknown primary cancer, nasopharynx cancer or salivary gland cancer
2. Metastatic disease
3. Another cancer within five years of study entry
4. Serious concomitant disease or medical condition
5. Pregnancy or lactation
6. Women of child-bearing potential with unclear contraception
7. Previous treatment with chemotherapy, radiotherapy or surgery in head and neck
8. Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 30 days prior to study screening
9. Life expectancy less than three months
10. Contraindications to receive cisplatin or cetuximab
11. Previous exposure to monoclonal antibodies and/or epidermal growth factor receptor (EGFR)-targeted therapy
12. Social situations that limit the compliance with study requirements

Date of first enrolment

10/06/2005

Date of final enrolment

31/12/2012

Locations**Countries of recruitment**

Germany

Netherlands

Study participating centre

Universitätsklinikum Rostock AÖR

Rostock

Germany

18059

Sponsor information

Organisation

Martin-Luther-University Halle-Wittenberg (Germany)

ROR

<https://ror.org/05gqaka33>

Funder(s)

Funder type

Industry

Funder Name

Merck Pharma GmbH Darmstadt (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration