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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

Registration date
22/08/2006

Overall study status
Completed

Last Edited
01/06/2009

Condition category
Cancer

[ ] Prospectively registered
[ ] 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date
10/06/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Added 01/06/2009: Phase I: 18, Phase II: 74

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)

Sponsor details
Medical Faculty
Magdeburger Strasse 27
Halle/Saale
Germany
06120

Sponsor type
University/education

Website
http://www.kks-halle.de

ROR
https://ror.org/05gqaka33

Funder(s)

Funder type
Industry

Funder Name
Merck Pharma GmbH 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