ISRCTN87356938 https://doi.org/10.1186/ISRCTN87356938

Radiotherapy (intensity-modulated radiation therapy [IMRT]), Erbitux® And CHemotherapy for unresectable carcinomas of head and neck

Submission date 23/04/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/06/2008	**Overall study status** Completed	
Last Edited 02/11/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Radiotherapy (intensity-modulated radiation therapy [IMRT]), Erbitux® And CHemotherapy for unresectable carcinomas of head and neck

Acronym
REACH

Study objectives
Exploratory approach: investigation on efficacy and safety of a combination of radiotherapy, Erbitux® and chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 13/01/2010: Ethics Committee of the Medical Faculty, University Hospital Heidelberg, approved on the 27th April 2009.

Study design
Single treatment group, open, multi-centre design

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Unresectable carcinomas of head and neck

Interventions
This is a single-arm trial. Treatment is a combination of:
1. Intensity-modulated radiotherapy, 1.8 Gy/day. Schedule of administration: study days 8 - 12, 15 - 19, 22 - 26, 29 - 33, 36 - 40 and 43 - 45 from study day 29 onwards; an additional concomitant boost will be given (1.5 Gy/day 29 - 33, 36 - 40 and 43 - 45)
2. Chemotherapy - carboplatin 70 mg/m^2 of body surface and 5-fluorouracil (5-FU) 600 mg/m^2

on study days 8 - 12 and 36 - 40
3. Cetuximab (Erbitux®): 400 mg/m^2 of body surface on study day 1 and 250 mg/m^2 on study days 8, 15, 22, 29, 36, 43

Total duration of treatment 45 days; total duration of follow-up: up to 60 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Erbitux®, chemotherapy (carboplatin, 5-fluorouracil [5-FU])

Primary outcome measure
Local-regional control.

All outcome measures will be determined at the same time during the study (follow-up visits):
1st follow-up: six weeks after completion of the treatment, i.e. after day 45
2nd follow-up: three months after 1st follow-up
3rd follow-up: three months after 2nd follow-up
4th and further follow-ups every six months for up to five years after trial beginning

Secondary outcome measures
1. Disease-free survival
2. Progression-free survival
3. Overall survival
4. Acute radiation effects
5. Late radiation effects
6. Adverse events
7. Proteomics and genomics

All outcome measures will be determined at the same time during the study (follow-up visits):
1st follow-up: six weeks after completion of the treatment, i.e. after day 45
2nd follow-up: three months after 1st follow-up
3rd follow-up: three months after 2nd follow-up
4th and further follow-ups every six months for up to five years after trial beginning

Overall study start date
30/09/2008

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Signed written informed consent
2. Aged 18 to 70 years, either sex
3. Life expectancy of at least six months

4. Ability of subject to understand character and individual consequences of clinical trial
5. Histologically confirmed locally advanced (stage III or IV), non-metastatic squamous cell carcinoma of the oro-, hypopharynx or larynx (T2-4, NX,M0)
6. Oral cavity or oro- or hypopharynx as the primary tumour site
7. At least one uni-measurable lesion according to the Response Evaluation Criteria In Solid Tumours (RECIST) criteria
8. Karnofsky Performances Status greater than 70%
9. Adequate bone marrow function:
9.1. Neutrophils greater than 1.5 x 10^9/L
9.2. Platelets greater than 100 x 10^9/L
9.3. Haemoglobin greater than 10.0 g/dL
10. Adequate liver function:
10.1. Bilirubin less than 2.0 g/dL
10.2. Serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), alkaline phosphatase (AP), gamma-glutamyl transferase (gGT) less than 3 x upper limit of normal (ULN)
11. Adequate renal function: serum creatinine less than 1.5 mg/dL
12. Negative serum/urine beta-human chorionic gonadotropin (B-HCG) test in women of childbearing potential
13. Women of childbearing potential: willingness to use effective contraceptive method, defined as the concomitant use of either an intrauterine pessary (IUP) or contraceptive pill and in both cases, condoms for the treatment duration and two months thereafter. Women of non-childbearing potiential are those who are post-menopausal for at least one year or sterilised
14. Men of procreative potential: willingness for effective prevention of procreation, defined as a use of condoms and a use of an intrauterine pessary (IUP) or a contraceptive pill by his partner for the treatment duration and two months thereafter
15. Subjects consent to collect blood samples for proteomics and genomics analysis. If a patient does not consent, no blood samples for proteomics and genomics will be taken. Nonetheless, he /she may be enrolled in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Previous chemotherapy, radiotherapy or surgery for carcinoma of the head and neck
2. Nasopharyngeal carcinoma
3. Prior exposure to epidermal growth factor receptor (EGFR) pathway targeting therapy
4. Other serious illness or medical conditions:
4.1. Unstable cardiac disease despite treatment

4.2. Congestive heart failure New York Heart Association (NYHA) grade 3 and 4
4.3. Significant neurologic or psychiatric disorders including dementia or seizures
4.4. Active disseminated intravascular coagulation
4.5. Other serious underlying medical conditions which in the opinion of investigator could impair the ability of the patient to participate in the study
4.6. Symptomatic peripheral neuropathy Common Toxicity Criteria (CTC) grade 2 or higher
4.7. Ototoxicity CTC grade 2 or higher, except if due to trauma or mechanical impairment due to tumour mass
5. Participation in other interventional trials within the last 30 days
6. Surgery within the last 30 days
7. Known allergic/hypersensitivity reaction to any drugs scheduled for the study treatment
8. Women: pregnant or breast-feeding
9. Known drug abuse
10. Other previous malignancy within five years, with exception of a history of a previous, adequately treated, basal cell carcinoma of the skin or pre-invasive carcinoma of the cervix
11. Legal incapacity or limited legal capacity
12. Medical or psychological condition which in the opinion of the investigator would not permit the patient to complete the study or sign meaningful informed consent

Date of first enrolment
30/09/2008

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Im Neuenheimer Feld 400
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Sponsor information

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University of Heidelberg (Germany)

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Sponsor type
University/education

Website
http://www.med.uni-heidelberg.de/index_eng.html

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Industry

Funder Name
Merck KGaA

Alternative Name(s)
Merck, Merck Group

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	interim results	02/04/2012		Yes	No
Protocol article		26/11/2010	02/11/2022	Yes	No