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Phase II study of cetuximab for the treatment of refractory or relapsed multiple myeloma: Erbitux for Multiple MyelomA (EMMA)

Submission date 30/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/09/2006	**Overall study status** Completed	
Last Edited 07/01/2021	**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
NCT00368121

Secondary identifying numbers
EMMA-1

Study information

Scientific Title
Phase II study of cetuximab for the treatment of refractory or relapsed multiple myeloma: Erbitux for Multiple MyelomA (EMMA)

Acronym
EMMA-1

Study objectives
Efficacy of Erbitux in relapsed or refractory multiple myeloma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics commission of the Medical Faculty of the University Hospital of Cologne, approval received on 03/08/2006 (reference number: 06-062).

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

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Relapsed or refractory multiple myeloma

Interventions
Cetuximab (Erbitux) loading dose of 400 mg/m2, followed by weekly doses of 250 mg/m2. Cetuximab will be administered once weekly by intravenous infusion.

Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
To assess efficacy of Cetuximab in patients with refractory/relapsed multiple myeloma.

Secondary outcome measures
1. Safety profile of Cetuximab with/without Dexamethasone
2. Freedom from treatment failure
3. Progression-free survival
4. Overall survival
5. Pharmacogenomic evaluation of response to treatment

Overall study start date
01/03/2006

Completion date
30/11/2009

Eligibility

Key inclusion criteria
1. Multiple myeloma diagnosed according to the Durie-criteria in stage II or III (Salmon and Durie)
2. Measurable disease
3. Refractory or relapsed disease after at least one line of treatment
4. Male or female 18 years of age or older
5. Life expectancy more than 12 weeks
6. Eastern Cooperative Oncology Group (ECOG) performances status zero to two
7. If of childbearing potential, willingness to use effective contraceptive method for the study duration and six months post-dosing
8. No surgery, radiotherapy or chemotherapy or any investigational agent within four weeks of study entry
9. Signed written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
33

Total final enrolment

Key exclusion criteria
1. Asecretory multiple myeloma
2. Patients eligible and willing to undergo high dose chemotherapy followed by autologous stem cell transplantation
3. Prior allogenic transplantation
4. Prior antibody or Epidermal Growth Factor Receptor (EGFR)-pathway targeting therapy
5. Severe cardiovascular disease like functionally restricting heart rhythm disturbance or heart malformation or severe hypertension, or cardiac insufficiency more than the New York Heart Association-II
6. Human Immunodeficiency Virus (HIV) infection, Hepatitis B or C
7. Brain disorders, psychatric illness
8. Insufficient bone marrow reserve (leucocytes less than 1500/µl, thrombocytes less than 50000 /µl)
9. Creatinine-clearance less than 50 ml/min or serum creatinine more than 1.8 mg/dl
10. Bilirubin more than 2 mg/dl, Aspartate aminotransferase (AST) and Alanine aminotransferase (ALT) more than 100 U/l
11. Pregnancy (absence confirmed by serum/urine Beta-Human Chorionic Gonadotropin [Beta-HCG]) or breast-feeding
12. Pulmonary dysfunction
13. Active secondary malignancy
14. Legal incapacity or limited legal capacity
15. Having participated in another clinical trial or any investigational agent in the preceding 30 days
16. Known allergic/hypersensitivity reaction to any compounds of the treatment
17. Other previous malignancy within five years, with exception of a history of a previous basal cell carcinoma of the skin or pre-invasive carcinoma of the cervix
18. 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
19. Known drug abuse/alcohol abuse

Date of first enrolment
01/03/2006

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital of Cologne
Cologne
Germany
50937

Sponsor information

Organisation
University of Cologne (Germany)

Sponsor details
Kerpener Str. 62
Cologne
Germany
50937

Sponsor type
University/education

ROR
https://ror.org/00rcxh774

Funder(s)

Funder type
Industry

Funder Name
Merck Pharma GmbH (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?
Results article	results	01/03/2014	07/01/2021	Yes	No