

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/01/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00368121

Protocol serial number
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).

Primary study design

Interventional

Study design

Open-label, non-randomised phase II study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

15

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, psychiatric illness
8. Insufficient bone marrow reserve (leucocytes less than 1500/ μ l, thrombocytes less than 50000/ μ l)
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)

ROR

<https://ror.org/00rcxh774>

Funder(s)

Funder type

Industry

Funder Name

Merck Pharma GmbH (Germany)

Results and Publications

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