Phase II study of Cetuximab combined with Cisplatin or Carboplatin/Pemetrexed as first line treatment in patients with malignant pleural mesothelioma

Published: 07-12-2010
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By adding Cetuximab to standard treatment, we hope to prolonge progression free survival

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mesotheliomas
Study type	Interventional

Summary

ID

NL-OMON34616

Source
ToetsingOnline

Brief title
MesoMab

Condition

- Mesotheliomas

Synonym
malignant mesothelioma or cancer of the mesothelium

Research involving
Human

Sponsors and support

Primary sponsor: Atrium MC Heerlen
Source(s) of monetary or material Support: Universitair Ziekenhuis Gent;België (overall sponsor studie)

Intervention

Keyword: Cetuximab, Chemotherapy, First line, Mesothelioma

Outcome measures

Primary outcome

Progression fee survival rate at 18 weeks

Secondary outcome

- Response rate according to modified RECIST criteria

- Toxicity (CTCAE version 4)

- Overall survival

Study description

Background summary

Multicenter , open phase 2 study on Standardly, 4 to 6 cycles of palliative chemotherapy, platinum in combination with pemetrexed, are given. Despite of this treatment, median survival is poor (9-12 months). By combining conventional cytotoxic agents with a novel agent, hopefully treatment and survival can be approved. Cetuximab or Erbitux is a monoclonal antibody against the EGFR (Epidermal Growth Factor Receptor). By blocking the receptor, it interferes with cel growth and division. Most mesothelioma show a strong expression of the EGFR protein. Apart from that, Cetuximab also has antibody-dependent cell-mediated cytotoxicity (ADCC).
The translation research program consists of the determination of EGFR- and K-Ras mutations on the tumor tissue and the correlation with outcome.

Study objective

By adding Cetuximab to standard treatment, we hope to prolonge progression free survival

Study design

Patients will be treated with standard chemotherapy, combined with Cetuximab weekly. After a maximum of 6 cycles of chemotherapy, administration of Cetuximab will be continued until disease progression. Every 6 weeks, a CT scan

will be done to evaluate therapy.

Intervention

A. Physical examination: weekly during in maintenace and every 3 months during follow up
B. Pulmonary function test: baseline and 18 weeks after initiating therapy
C. CT scan thorax and upper abdomen: every 6 weeks during maintenance
D. Blood sampling: weekly during maintenace treatment with cetuximab

Study burden and risks

Burden and risks consist of the adverse events associated: most common are rash, allergic reactions and lung problems. Other, less frequent are fatigue, dyspnea, headache, vomiting and mucositis (mouth for example).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histologically proven malignant pleural mesothelioma, epitheloid subtype
- Recurrent after radical surgery or disease not considered suitable for radical treatment
- EGFR IHC + as assessed by DAKO kit with at least 1% of cells showing staining
- Performance status WHO 0 or 1
- Life expectancy > 12 weeks
- Weight loss < 10% in last 3 months
- Adequate bone marrow reserve, renal and hepatic function
- Measurable disease (modified RECIST)
- No prior chemotherapy
- No prior or other malignancies, except if longer than 5 yrs ago and adequately treated or basocellular skin or in situ cervical cancer
- No uncontrolled infection
- Written informed consent.
- Male/Female
- > 18 years

Exclusion criteria

- Evidence of brain or leptomeningeal metastases
- Patients who are unable to interrupt aspirin, other nonsteroidal anti-inflammatory drugs for a 5-day period starting 2 days before administration of pemetrexed (8-day period for long acting agents such as piroxicam)
- Patients that cannot be treated with folic acid and vitamin B 12
- Patients that cannot be treated with dexamethasone.
- Presence of clinically detectable (by physical examination) third-space fluid collections, for example ascites of pleural effusions that cannot be controlled by drainage or other procedures prior to the study entry.
- Use of investigational drugs
- Pregnant or lactating women

Study design

Design

Study phase:	2
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cetuximab
Generic name:	Erbitux
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-12-2010
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	09-05-2011
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	2009/337
EudraCT	EUCTR2009-014293-17-NL
CCMO	NL32991.096.10