Non invasive imaging of Cetuximab-Zirconium-89 uptake with Positron-Emission-Tomography (PET) scans: A phase I trial in stage IV cancer patients.

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To determine the toxicity of Zirconium-89 (Zr89) labelled Cetuximab in patient with stage IV cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON35426

Source
ToetsingOnline

Brief title
89ZR-Cetuximab in stage IV NSCLC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
stage IV cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: Keizerfonds

Intervention

Keyword: Cetuximab, NSCLC, Stage IV, Zirconium-89

Outcome measures

Primary outcome

MTD (Maximum Tolereerbare Dosis) Zirconium-89 labelled Cetuximab in patients

with stage IV cancer

Secondary outcome

Toxicity (CTCAE 3.0)

Optimalisation of tumour visualization

Study description

Background summary

Cetuximab has in the past proven to contribute to a better tumour controle. By visualizing the tumour it can be examined better. Therefore Cetuximab is labelled to 89-Zirconium.
The safety of this labelled 89-Zirconium-Cetuximab is being examined with this trial.

Study objective

To determine the toxicity of Zirconium-89 (Zr89) labelled Cetuximab in patient with stage IV cancer.

Study design

Phase I study with escalating doses Zirconium-89 labelled Cetuximab.

Day 0: Patients receive first dosis of Cetuximab (400 mg/m2) and Zirconium-89 labelled Cetuximab (60 MBq, 10 mg)
Day 4,5 en 6: PET-CT scans

Day 14: patients receive second dosis of Cetuximab (250m g/m2) and Zirconium-89 labelled Cetuximab (120 MBq, 10 mg)
Day 18, 19 en 20: PET-CT scans

Patients included in step 1 and 2 are not selected on basis of EGFR overexpression. Therefore, if the secondary endpoint, being image quality, cannot be assessed due to the absence of EGFR overexpression in any of the primary tumours, a third step will be added in which 3 patients are included before the start of any treatment, with an EGFR overexpressing tumour on immunohistochemistry.

Step 3 (3 patients): Determination of the image quality in untreated patients with tumours overexpressing EGFR
A standard loading dose of 400 mg/m2 of cetuximab will be administered in 3 patients, a part labelled with 89Zr (120MBq, 10mg). After the injection, visualization of all tumour sites will be analyzed by
performing a PET-CT scan on day 4, 5 or 6 post injection, based on the optimal TBR in step 1 and 2.

Intervention

Eligible patients receive an intravenous dose of Cetuximab and Zirconium-89 labelled Cetuximab twice.
Furthermore blood is drawn twice a week during the study.

Study burden and risks

Patients receive an intravenous dose of Cetuximab and Zirconium-89 labelled Cetuximab twice. Rarely an allergic reaction can occur from the infusion.
Extra PET-CT scans are made 6 times during the study.
Twice an week blood is drawn during the study.

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

- Histological or cytological confirmed stage IV cancer
- Primary or recurrent stage IV (UICC 2002; sixth edition)
- WHO Performance 0-2
- Measurable cancer on PET-scan, i.e. index lesion with a volume of at least 6cm3
- No recent severe cardiac disease
- Adequate bone marrow
- Adequate renal function
- Adequate hepatic function
- Life expectancy > 3 months
- Willing and able to comply with study prescriptions
- 18 years or older
- Not pregant or breast feading
- Written informed consent
- No previous administration of Cetuximab

Exclusion criteria

- Mixed pathology (non-small cell lung cancer plus small cell lung cancer)
- Recent myocardial infarction
- Uncontrolled infectious disease
- Less than 18 years old
- Other active malignancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-06-2009
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	89Zr-cMAb-U36 (=89Zirconium-labelled Cetuximab)
Generic name:	89Zr-cMAb-U36 (=89Zirconium-labelled Cetuximab)
Product type:	Medicine
Brand name:	Erbitux
Generic name:	Cetuximab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	06-10-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-10-2008
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-07-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-09-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-10-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2007-006376-10-NL
ClinicalTrials.gov	NCT00691548
CCMO	NL21891.068.08