

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

Published: 06-10-2008

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	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/m<sup>2</sup>) 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/m<sup>2</sup>) 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/m<sup>2</sup> 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**

### **Public**

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### **Scientific**

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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 6cm<sup>3</sup>
- 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 pregnant or breast feeding
- 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