# Cisplatin or Cetuximab and conventional versus redistributed radiation for advanced head and neck cancer

Published: 31-05-2011
Last updated: 29-04-2024

This Phase II trial aims to:1 Test the predictive value of Zr89 Cetuximab uptake in vivo for treatment specific outcome 2 Explore the impact of dose redistribution on loco-regional control and disease free survival.If individualized treatment...

| | |
|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Respiratory and mediastinal neoplasms malignant and unspecified |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON36211

**Source**
ToetsingOnline

**Brief title**
ARTFORCE

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)

**Synonym**
head and neck cancer, Oropharyngeal cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Nederlands Kanker Instituut
**Source(s) of monetary or material Support:** EU en KWF

## Intervention

**Keyword:** chemotherapy, combined modality treatment, head and neck cancer, radiotherapy

## Outcome measures

### Primary outcome

1. Primary Endpoints

a. Locoregional recurrence free survival at two years

b. Correlation of anatomical distribution of Zr89 Cetuximab uptake with

treatment arm and anatomical location of recurrence

### Secondary outcome

2. Secondary Endpoints

a. Quality of life during and after treatment, at 6 months and one year

b. Swallowing function preservation at one year

c. Progression Free Survival

d. Overall Survival

e. Toxicity

# Study description

### Background summary

The standard treatment for advanced head and neck carcinoma is Radiotherapy with concomitant cisplatin. Combination of Radiation with Cetuximab also yields better results than RT alone. It is unlikely however that the benefit concerns exactly the same patients. Ultimate goal of the trial is to predict efficacy of both treatments on beforehand in order to select the optimal treatment for a patient and avoid unnecessary toxicity. It is also anticipated that adaptive inhomogeneous dose distribution (redistribution) with higher radiation doses on PET GTV areas will also contribute to improved locoregional progression free

survival with equal toxicity.

### Study objective

This Phase II trial aims to:
1 Test the predictive value of Zr89 Cetuximab uptake in vivo for treatment specific outcome
2 Explore the impact of dose redistribution on loco-regional control and disease free survival.

If individualized treatment appears to be feasible, a phase III trial will be executed to challenge the concept.

### Study design

The trial consist of four treatment arms, each 90 patients (i.e. 4x90 patients).

For all patients: 1x Zr89-Cetuximab 400 mg/m2 (pre RT)
Patients will be randomized between:
1 Cisplatin (weekly 40 mg/m2)
Radiotherapy (IMRT) 51.8 (elective)-70 (boost) Gy 35 fractions.
2 Cisplatin: (weekly 40 mg/m2)
Radiotherapy (adaptive IMRT) 51.8 (elective)-67 (64-70) (boost) - 84 (boost on PET- GTV) Gy 35 fractions
3 Cetuximab
6x Cetuximab (weekly 250mg/m2)
Radiotherapy (IMRT) 51.8 (elective)-70 (boost) Gy 35 fractions.
4 Cetuximab
6x Cetuximab (weekly 250mg/m2)
Radiotherapy (adaptive IMRT) 51.8 (elective) - 67 (64-70) (boost) - 84 (boost PET-GTV) Gy 35 fractions

### Study burden and risks

The patients with cisplatin and radiotherapy treatment undergo an additional Zr labelled Cetuximab scan this takes around 4 Hrs.
All patients are asked to fill out Quality of Life questionnaires.

## Contacts

**Public**
Nederlands Kanker Instituut

Plesmanlaan121

1066 CX Amsterdam
NL
**Scientific**
Nederlands Kanker Instituut

Plesmanlaan121
1066 CX Amsterdam
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Stage III-IV T3-4 SCC Head and Neck, Oropharynx, Oral Cavity or Hypopharynx, Eligible for chemoradiation

## Exclusion criteria

Inability to receive one of the treatment arms, laryngeal cancer, previous malignancies

# Study design

## Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Observational non invasive |

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 0 |
| Type: | Anticipated |

## Ethics review

Not approved

| | |
|---|---|
| Date: | 31-05-2011 |
| Application type: | First submission |
| Review commission: | PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam) |

## 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 |
|---|---|
| CCMO | NL36782.031.11 |