# An exploratory, open label, multicenter study to investigate pharmacodynamic of RO5083945, a human monoclonal antibody antagonist of Epidermal Growth Factor Receptor (EGFR), compared to cetuximab in patients with operable head and neck squamous cell carcinoma.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34195

**Source**
ToetsingOnline

**Brief title**
BP22350

### Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

**Synonym**

operable head and neck squamous cell carcinoma

**Health condition**

hoofd hals carcinoom

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Roche Nederland B.V.
**Source(s) of monetary or material Support:** Roche Nederland B.V.

## Intervention

**Keyword:** EGFR, Exploratory, Head and neck carcinoma, Pharmacodynamic

## Outcome measures

**Primary outcome**

- Immune cell infiltration

- Immune cell activation

**Secondary outcome**

- Maturation of human T-cell lymphocytes

- NK cell lytic activity and activation

- Human T-regulatory test

- Determine gene expression profiles

- Determine new circulating factors/potential pharmacodynamic biomarkers, like

circulating tumor cells or mutant DNA

- Correlation bewteen antibody polymorfisms and PD parameters

- Anti-cancer activity by PET/CT

- Comparison of cetuximab and RO5083945 responses

- Correlation between PK and PD, effucay and safety

- Safetyprofile of RO5083945

# Study description

### Background summary

Worldwide, the tumor burden of head and neck squamous cel carcinoma (HNSCC) is substantial, with over 500.000 new cases diagnosed anually. Surgery and/or chemoradiotherapy are commonly used to treat locally advaced disease. However, a considerable portion of patients relapse, with tumor growth either locally or at distant sites, following initial treatment. EGFR plays a role in patients with HNSCC. Studying the rol of EGFR antagonists, like cetuximab and RO5083945 is therefore very important.

### Study objective

This study looks at the impact of RO5083945 compared to cetuximab in patients with HNSCC. The study also evaluates the behavior of these drugs within the body and their mechanism of action on head and neck tumor cells and on the immune system cells.

### Study design

Exploratory, open-label study with two arms, in which one arm receives cetuximab and the other arm RO5083945 during surgery waiting time.

### Intervention

One of the two arms receives cetuximab (400 mg/m² [1e infuus] / 250 mg/m² [2e en volgend infuus]) each week, with a maximum of 3 infusions. The other arm receives RO5083945 (1400 mg) each week, with a maximum of 3 infusions.

### Study burden and risks

each week the patient receives a i.v. infusion of RO5083945 or cetuximab, with a maximum of 3 infusions per study. After the last infusion the tumor will be surgically removed. A screening and before surgery, a PET/CT scan is carried out to access the tumor. Furthermore, tumor and skin biopsies will be taken during screening and before surgery. At screening, before each infusion, before surgery and after the treatment has stopped, blood samples will be drawn, physical exam is carried out and adverse events will be registered. When the patient consented for the Roche Clinical Repository (RCR) part of the study, blood samples will be drawn at screening, before infusion 2 and 3 and before

surgery.

## 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

1. Signed Informed consent
2. Age >=18 years
3. Able and willing to comply with the protocol
4. Histologically confirmed squamous cell carcinoma
5. naive for chemaotherapy and radiotherapy
6. Tumor T2-4, any N, M0 disease. Tumore must be considered resectable in a curative intent with a planned surgical excision
7. Last administration of a corticosteriod or an antihistamine >= 14 days prior to RO5083945/cetuximab infusion

### Exclusion criteria

1. Carcinoma of nasal cavity, paranasal sinus and nasopharynx
2. Recurrent squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx or larynx
3. Concurrent therapy with any other investigational product
4. Pregnant or lactating women
5. Hypersensitivity to the active substance or to any of the excipients
6. Uncontrolled diabetes
7. Poorly controlled hypertension
8. Patients with serious uncontrolled intercurrect illness including poorly controlled diabetes mellitus, active or uncontrolled infection
9. Known positivity for HIV, hepatitis B and /or hepatitis C infections
10. Any other disease that contraindicates the us eof an investigational drug or that may affect the interpretation of the results or render the patient at high risk from treatment complications
11. Patients with dementia or altered mental status
12. Major surgery >= 4 weeks prior to study day 1

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| 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: | 6 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |

| | |
|---|---|
| Brand name: | Erbitux |
| Generic name: | Cetuximab |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 27-10-2010 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 22-02-2011 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 24-02-2011 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | BP22350 |
| EudraCT | EUCTR2009-012656-25-NL |
| CCMO | NL34166.091.10 |