# Onderzoek naar de werkzaamheid van toevoeging van Cetuximab aan de combinatie van radiotherapie en Cisplatin bij patiënten met niet-kleincellig longkanker.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21439

**Source**
NTR

**Brief title**
RADITUX

**Health condition**

Cetuximab, non-small lung carcinoma, cisplation, radiotherapy, locally advanced

### Sponsors and support

**Primary sponsor:** NKI-AVL
**Source(s) of monetary or material Support:** MERCK-SERONO

### Intervention

### Outcome measures

**Primary outcome**

The clinical activity of Cetuximab CCRT locally advanced NSCLC (as defined by the objective rate of local control (OLRC)).

### Secondary outcome

1. The safety profile of Cetuximab in combination with concurrent chemo-radiotherapy;

2. Overall survival (OS);

3. Progression free survival (locoregional/distant) (PFS);

4. Duration of overall response;

5. Response duration;

6. Adverse events.

## Study description

### Background summary

CCRT is the treatment of choice for patients with locally advanced NSCLC. To improve outcome this trial will combine standard CCRT with the EGFR-monoclonal antibody Cetuximab, that has shown promissing results in both advanced NSCLC and in combination with radiotherapy in Head and Neck cancer. This trial is designed as a two steps study with a feasibility part and a randomized phase II study comparing CCRT with CCRT plus Cetuximab.

### Study objective

The addition of the EGFR monoclonal antibody Cetuximab to standaard concurrent chemoradiotherapy improves the outcome of treatment of locally advanced non-small lung carcinoma.

### Study design

January 2008: Start feasibility study. Three months after closure of feasibility phase the second phase will start.

Last patient: January 2010.

Follow-up duration: Twelve months or until disease progression.

### Intervention

Addition of Cetuximab to standard concurrent chemoradiotherapy (CCRT). Standard CCRT consists of Daily dosing of Cisplatin (6mg/m2) and radiotherapy (2.75Gy) during 24 consecutive days excluding the weekends. Cetuximab is given at a loading dose of 400mg/m2 one week prior to the start of CCRT and is then given at a weekly dose of 250mg/m2 during 5 weeks concomitantly to the CCRT.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. >= 18 years of age;

2. Histologically or cytologically confirmed diagnosis of NSCLC;

3. Stage II/III non-operable disease, without malignant pleural effusion;

4. Presence of at least one measurable target lesion;

5. Acceptable pulmonary function as defined by a Fev1 of >=30% and a DLCO of > 40% of predicted;

6. WHO performance 0-1;

7. Life expectancy of at least 6 months;

8. Adequate haematological, renal and hepatic functions:

A. Absolute neutrophil count > 2x109/l;

B. Platelet count > 100 x 109/l;

C. Total bilirubin < 2 x UNL;

D. ASAT/ALAT < 3 x UNL;

E. Alkaline phosphatase < 5 x UNL;

F. Creatinine < 130 ¦Ìmol/l or creatinine clearance > 50 ml/min; measured or calculated;

G. Urine dipstick for proteinuria < 1+. If urine dipstick is ¡Ý 1, 24 hour urine must demonstrate < 500 mg of protein in 24 hours.

9. No pre-existing sensory neurotoxicity grade >= 2 (CTC);

10. Patients of reproductive potential must agree to practice an effective medically approved contraceptive method during the trial and 3 months afterwards;

11. Expected risk of radiation-induced pulmonary toxicity is not high: V20 =< 36% / MLD =< 20%;

12. Signed written informed consent.

## Exclusion criteria

1. Concurrent active malignancy other than localized, non-melanoma skin cancer or carcinoma-in-situ of the cervix (unless definitive treatment was completed 5 years or more before study entry and the patient has remained disease free);

2. Prior:

A. Ipsilateral radiotherapy to the chest;

B. Chemotherapy within the last 5 years;

C. Immunotherapy or treatment with murine monoclonal antibodies, Cetuximab, or other EGFR inhibitors.

3. Pregnant or breast-feeding patients;

4. WHO performance score > 1;

5. Other serious diseases, such as heart failure, angina pectoris, myocardial infarction within the last 6 months, uncontrolled hypertension;

6. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be assessed with the patient before registration in the trial;

7. Participation in other trial with investigational drug or treatment modality.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 13-02-2008 |
| Enrollment: | 110 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 19-02-2010 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL2113 |
| NTR-old | NTR2230 |
| Other | NKI-AVL : M07CCL |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A