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

Gepubliceerd: 19-02-2010 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21439

Bron
NTR

Verkorte titel
RADITUX

Aandoening

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

Ondersteuning

Primaire sponsor: NKI-AVL
Overige ondersteuning: MERCK-SERONO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-02-2008
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2113
NTR-old	NTR2230
Ander register	NKI-AVL : M07CCL
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A