A phase II study of erlotinib and bevacizumab in patients with locally advanced and/or metastatic (stage IIIB or IV) Non-Small Cell Lung Cancer (NSCLC) who have not received prior chemotherapy.

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Tumor response from erlotinib and bevacizumab as first line treatment in advanced NSCLC will result in “non-progressive disease” within 6 weeks in more than 50% of patients.

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

Samenvatting

ID

NL-OMON22641

Bron
NTR

Verkorte titel
Phase II study of erlotinib and bevacizumab as first line treatment in patients with advanced NSCLC.

Aandoening

Non-Small Cell Lung Cancer

Ondersteuning

Primaire sponsor: Roche
Overige ondersteuning: Scientific grant Roche Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficacy of erlotinib and bevacizumab in first line treatment of NSCLC as determined by the rate of no progression at 6 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

An open label, multicenter, phase II study of erlotinib and bevacizumab in patients with locally advanced and/or metastatic NSCLC who have not received prior chemotherapy.
Primary objective: Efficacy of combination of erlotinib and bevacizumab as determined by the rate of no progression at 6 weeks.
Secundary objectives: Efficacy of erlotinib and bevacizumab as determined by
-the objective response rate and disease control rate
-duration of response
-time to disease progression or death
-survival
-safety of erlotinib and bevacizumab
Number of patients: 46 patients
Study population: Cytologically or histologically advanced non-squamous NSCLC. Patients with squamous cell histology are eligible only if their intrathoracic disease has been completely resected, they have no current evidence of intrathoracic disease (with the exception of isolated pleural effusion), and they have not had hemoptysis in the 28 days prior to randomization.

Doel van het onderzoek

Tumor response from erlotinib and bevacizumab as first line treatment in advanced NSCLC will result in “non-progressive disease” within 6 weeks in more than 50% of patients.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

All patients will receive:

1. Erlotinib 150 mg/day orally;

2. Bevacizumab 15 mg/kg every 3 weeks as a 90 minutes infusion.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Cytologically or histologically advanced non-squamous NSCLC. Patients with squamous cell histology are eligible only if their intrathoracic disease has been completely resected, they have no current evidence of intrathoracic disease (with the exception of isolated pleural effusion), and they have not had hemoptysis in the 28 days prior to randomization;

2. No prior chemotherapy or therapy with systemic anti-tumor therapy (e.g., monoclonal antibody therapy) or prior exposure to agents directed at the HER axis (e.g. EGFR TK inhibitors, Herceptin). Prior surgery and/or localized irradiation is permitted provided that the irradiated lesion is not the only measurable lesion;

3. Measurable disease as defined by RECIST criteria;

4. Age 18 or greater;

5. ECOG performance status of 0-2;

6. Life expectancy of at least 12 weeks;

7. At least 4 weeks since any prior surgery or radiotherapy. Patients who, in the opinion of the investigator, have fully recovered from surgery in less than 4 weeks may also be considered for the study. Patients must have recovered (CTC =< 1) from acute toxicities of any previous therapy;

8. Neutrophils >= 1.5 x 109/L and platelets > 100 x 109/L;

9. Serum bilirubin =< 1.5 upper limit of normal (ULN). ASAT/ALAT =< 2.5 x ULN (in case of livermetastases =< 5 x ULN), Alkaline phosphatase =< 2.5 x ULN;

10. Serum creatinine =< 1.5 ULN or creatinine clearance >= 60 ml/min;

11. Urine dipstick for proteinuria < 2+. Patients discovered to have >=2+ proteinuria on dipstick urinalysis at baseline, should undergo a 24-hour urine collection and must demonstrate =< 1 g of protein/24hr;

12. Normal serum calcium;

13. Able to comply with study and follow-up procedures;

14. Able to take oral medication;

15. For all females of childbearing potential a negative pregnancy test must be obtained within 48 hours before registration starting therapy;

16. Patients with reproductive potential must use effective contraception;

17. Written Informed Consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, severe cardiac arrhythmia requiring medication, hepatic, renal or metabolic disease);

2. Evidence of tumour invading major blood vessels;

3. Major surgical procedure, open biopsy or significant traumatic injury within 28 days prior to

Day 0
(Patients must have recovered from any major surgery), or anticipation of need for major surgical procedure during the course of the study;

4. Planned radiotherapy for underlying disease (prior completed radiotherapy treatment allowed);

5. Serious non-healing wound or ulcer;

6. Evidence of bleeding diathesis or coagulopathy. Presence of a cavitary lesion or evidence of tumor invading or abutting major blood vessels;

7. Brain metastasis or spinal cord compression that is newly diagnosed and/or has not yet been treated with surgery and/or radiation; previously diagnosed and treated CNS metastases or spinal cord compression with evidence of stable disease for at least 2 months is permitted;

8. Patients who cannot take oral medication, who require intravenous alimentation, have had prior surgical procedures affecting absorption, or have active peptic ulcer disease;

9. History of hemorrhagic disorders;

10. Current or recent (within 10 days prior to study treatment start) ongoing treatment with anticoagulants for therapeutic purposes i.e. except for anticoagulation for maintenance of patency of permanent indwelling IV catheters;

11. History of >= grade 2 hemoptysis (symptomatic and medical intervention indicated);

12. Ongoing treatment with aspirin (> 325 mg/day) or other medications known to predispose to gastrointestinal ulceration;

13. Nursing mothers.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	46
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	01-12-2005
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	NL486
NTR-old	NTR528
Ander register	: N/A
ISRCTN	ISRCTN78329606

Resultaten

Samenvatting resultaten

N/A