Fase II studie van sorafenib bij patienten met een gemetastaseerd niet-kleincellig bronchuscarcinoom die progressief zijn na voorafgaande behandeling met cisplatina bevattende chemotherapie waarvan de tumor een K-Ras mutatie bevat.

Gepubliceerd: 22-09-2010 Laatst bijgewerkt: 19-03-2025

Sorafenib has significant clinical activity in K-Ras mutated NSCLC.

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

Samenvatting

ID

NL-OMON25401

Bron
NTR

Aandoening

Non-Small Cell Lung Cancer

Ondersteuning

Primaire sponsor: Vrije Universiteit Medisch centrum
Postbus 7057
1007 MB
Amsterdam
Netherlands
Overige ondersteuning: fonds = verrichter = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Rate of non-progression at 6 weeks according to the RECISCT criteria.

Toelichting onderzoek

Achtergrond van het onderzoek

A phase II study of sorafenib in patients with locally advanced and/or metastatic (stage IIIB or IV) non-small cell lung cancer (NSCLC) harbouring a k-ras mutation.

Indication: Advanced (stage IIIB or IV) NSCLC harbouring a k-ras mutation.

Objectives: Disease Control Rate. Efficacy of sorafenib as determined by:

1. Objective response rate;

2. Duration of response;

3. Time to disease progression or death;

4. Survival

Trial Design: An open-label, multicenter, phase II study of erlotinib and sorafenib.

Number Of Patients: 16 patients in first cohort, 48 patients in total based on interim evaluation.

Number of Centres: 6 (Maastricht University Medical Center, Vrije Universiteit Medical Center Amsterdam, University Medical Centre Groningen, Netherlands Cancer Institute Amsterdam, Erasmus Medical Centre, Rotterdam, Academic Medical Centre, Amsterdam).

Target Population: Advanced NSCLC patients.

Patient Selection Criteria: Cytologicly Histologically advanced NSCLC harbouring a k-ras mutation.

Length Of Study: Approximately 12 months for accrual and 6 months for follow-up but at least until disease progression is recorded for all patients.

All patients will receive Sorafenib 400 mg bid.

Doel van het onderzoek

Sorafenib has significant clinical activity in K-Ras mutated NSCLC.

Onderzoeksopzet

Every three weeks.

Onderzoeksproduct en/of interventie

Sorafenib 400 mg bd untill disease progression.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Histologically advanced NSCLC stage IIIB or IV harbouring a K-RAS mutation;

2. Disease progression after at least 1 prior chemotherapy regimen that should include a platinum doublet;

3. Prior surgery and/or localized irradiation is permitted provided that the irradiated lesion is not the only measurable lesion;

4. Age > 18 years;

5. ECOG Performance Status of 0-2;

6. Life expectancy of at least 12 weeks;

7. Subjects with at least one uni-dimensional (for RECIST) measurable lesion. Lesions must be measured by CT-scan;

8. Adequate bone marrow, liver and renal function as assessed by the following laboratory requirements to be conducted within 7 days prior to screening:

A. Hemoglobin > 9.0 g/dl;

B. Absolute neutrophil count (ANC) >1,500/mm3;

C. Platelet count ≥ 100,000/µl;

D. Total bilirubin < 1.5 times the upper limit of normal;

E. ALT and AST < 2.5 x upper limit of normal (< 5 x upper limit of normal for patients with liver involvement of their cancer);

F. Alkaline phosphatase < 4 x ULN;

G. PT-INR/PTT < 1.5 x upper limit of normal [Patients who are being therapeutically anticoagulated with low molecular weight heparin will be allowed to participate provided that no prior evidence of underlying abnormality in these parameters exists.];

H. Serum creatinine < 1.5 x upper limit of normal.

9. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Excluded medical conditions:

1. History of cardiac disease: congestive heart failure >NYHA class 2; active CAD (MI more than 6 mo prior to study entry is allowed); cardiac arythmias requiring anti-arythmic therapy (beta blockers or digoxin are permitted) or uncontrolled hypertension;

2. History of HIV infection or chronic hepatitis B or C;

3. Active clinically serious infections (> grade 2 NCI-CTC version 3.0);

4. Symptomatic metastatic brain or meningeal tumors (unless the patient is > 1 months from definitive radiotherapy and off steroids);

5. Patients with seizure disorder requiring medication (such as steroids or anti-epileptics);

6. History of organ allograft;

7. Patients with evidence or history of bleeding diasthesis;

8. Patients undergoing renal dialysis;

9. Previous or concurrent cancer that is distinct in primary site or histology from the cancer being evaluated in this study EXCEPT cervical carcinoma in situ, treated basal cell carcinoma, superficial bladder tumors [Ta, Tis & T1] or any cancer curatively treated > 3 years prior to study entry.

Excluded therapies and medications, previous and concomitant:

1. Anticancer chemotherapy or immunotherapy during the study or within 3 weeks of study entry;

2. Radiotherapy during study or within 3 weeks of start of study drug. (Palliative radiotherapy will be allowed). Major surgery within 3 weeks of start of study;

3. Autologous bone marrow transplant or stem cell rescue within 4 months of study;

4. Use of biologic response modifiers, such as G-CSF, within 3 week of study entry. [G-CSF and other hematopoietic growth factors may be used in the management of acute toxicity such as febrile neutropenia when clinically indicated or at the discretion of the investigator, however they may not be substituted for a required dose reduction.] [Patients taking chronic erythropoietin are permitted provided no dose adjustment is undertaken within 2 months

prior to the study or during the study];

5. Investigational drug therapy outside of this trial during or within 4 weeks of study entry;

6. Prior exposure to the study drugs;

7. Pregnant or breast-feeding patients. Women of childbearing potential must have a negative pregnancy test performed within 7 days of the start of treatment. Both men and women enrolled in this trial must use adequate barrier birth control measures during the course of the trial and two weeks after the completion of trial;

8. Substance abuse, medical, psychological or social conditions that may interfere with the patient’s participation in the study or evaluation of the study results;

9. Any condition that is unstable or could jeopardize the safety of the patient and their compliance in the study;

10. Patients unable to swallow oral medications.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32472
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2422
NTR-old	NTR2530
CCMO	NL30000.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32472

Resultaten

Samenvatting resultaten
N/A