Hoog-gedoseerde, pulsatiele erlotinib na progressie op standaard dosering erlotinib bij EGFR-gemuteerde NSCLC patienten.

Gepubliceerd: 06-09-2012 Laatst bijgewerkt: 15-05-2024

High-dose, weekly erlotinib is a therapeutic option for EGFR-mutated NSCLC patients with leptomeningeal metastases while on EGFR-TKI therapy. In one of the patients treated with this dose schedule not only the leptomeningeal metastases showed...

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

Samenvatting

ID

NL-OMON20474

Bron
Nationaal Trial Register

Verkorte titel
PE study

Aandoening

Pulsatile
Erlotinib
NSCLC
EGFR mutation

Ondersteuning

Primaire sponsor: VU Medical Center
Overige ondersteuning: VU Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the objective response rate (ORR) at 8 weeks according to the response evaluation criteria in solid tumors (RECIST v1.1).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

High-dose, weekly erlotinib is a therapeutic option for EGFR-mutated NSCLC patients with leptomeningeal metastases while on EGFR-TKI therapy. In one of the patients treated with this dose schedule not only the leptomeningeal metastases showed evident response, but unexpectedly, the thoracic progression of disease showed evident response as well. This provides the rationale for this prospective trial; does erlotinib in a high-dose, weekly schedule show activity in EGFR-mutated NSCLC patients after being diagnosed with progression of disease while on standard dose EGFR-TKI therapy.

Objective:

To evaluate the effect of erlotinib 1500 mg weekly in EGFR-mutated NSCLC patients after being diagnosed with disease progression while on standard, daily dose of 150 mg erlotinib.

Study design:

Single-arm, open-label, phase II, intervention study.

Study population:

EGFR-mutated NSCLC patients, >18 years old.

Intervention:

Erlotinib 1500 mg once weekly.

Main study parameters/endpoints:

Primary objective: Disease control rate at 8 weeks.
Secondary objective: progression free survival at 6 months, overall survival at 1 year and toxicity according to CTC-AE 4.0.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Burden and risks associated with participation include outpatient visits every 4 weeks and a CT-scan every 8 weeks. Risks comprise the side effects of erlotinib, which are generally well manageable with best supportive care. Every outpatient visit physical examination will be performed, blood samples will be taken and every 8 weeks a CT-scan will be done. Risks are considered to be small, since there is much experience with erlotinib in this dose and schedule and side effects have been manageable.

Doel van het onderzoek

High-dose, weekly erlotinib is a therapeutic option for EGFR-mutated NSCLC patients with leptomeningeal metastases while on EGFR-TKI therapy. In one of the patients treated with this dose schedule not only the leptomeningeal metastases showed evident response, but unexpectedly, the thoracic progression of disease showed evident response as well. This provides the rationale for this prospective trial; does erlotinib in a high-dose, weekly schedule show activity in EGFR-mutated NSCLC patients after being diagnosed with progression of disease while on standard dose EGFR-TKI therapy.

Onderzoeksopzet

Every 8 weeks CT thorax.

Onderzoeksproduct en/of interventie

Erlotinib 1500 mg once a week. This will be given until progression of disease.

Contactpersonen

Publiek

Department of Pulmonary Diseases
VU University Medical Centre
PO Box 7057
E.F. Smit
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4444782

Wetenschappelijk

Department of Pulmonary Diseases
VU University Medical Centre
PO Box 7057
E.F. Smit
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4444782

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically confirmed stage IV non-squamous NSCLC patients;

2. Patients with an activating EGFR mutation who progressed on erlotinib or gefitinib monotherapy in daily dose of 150 mg or 250 mg respectively. (Patients with unknown mutation status that have exhibited a response to these agents or stable disease for at least 6 months while on treatment with gefitinib or erlotinib are also eligible);

3. Tumor biopsy available for EGFR mutation analysis at progression;

4. At least one measurable disease site, according to RECIST 1.1 criteria;

5. WHO performance status 0-2;

6. Willing and able to comply with the study prescriptions;

7. 18 years or older;

8. Not pregnant or breast feeding and willing to take adequate contraceptive measures during the study;

9. Ability to give and having given written informed consent before patient registration.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No uncontrolled infectious disease;

2. No other active malignancy;

3. No major surgery (excluding diagnostic procedures like e.g. mediastinoscopy or VATS biopsy) in the previous 4 weeks;

4. No treatment with investigational drugs;

5. No known prior hypersensitivity to erlotinib.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-09-2012
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36916
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3452
NTR-old	NTR3603
CCMO	NL41220.029.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36916

Resultaten

Samenvatting resultaten
N/A