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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20474

Source
Nationaal Trial Register

Brief title
PE study

Health condition

Pulsatile
Erlotinib
NSCLC
EGFR mutation

Sponsors and support

Primary sponsor: VU Medical Center
Source(s) of monetary or material Support: VU Medical Center

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. To assess progression-free survival (PFS) at six months;

2. To assess toxicity of high-dose erlotinib according to CTC AE 4.0.

Study description

Background summary

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.

Study objective

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.

Study design

Every 8 weeks CT thorax.

Intervention

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

Contacts

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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2012
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36916
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A