NVALT 16 Study

Study Title:
Iressa RE-challenge in advanced NSCLC EGFR mutated patients who responded to an EGFR-TKI used as first-line or previous treatment

Rationale:
Gefitinib is a registered first-line treatment for EGFR-mutated NSCLC patients. There is a lack of evidence for second and third line therapies in this category of patients. Several case reports have described successful re-administration of gefitinib to NSCLC patients who achieved objective response with the initial administration of gefitinib before eventual progression.

Objective:
The primary objective of this study is to evaluate the disease control rate (DCR; confirmed complete response (CR) or partial response (PR), or stable disease (SD)) of gefitinib using Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 in patients with activating sensitising Epidermal Growth Factor mutation positive (EGFR M+) NSCLC. The secondary objectives of the study are: objective response rate (ORR) according to RECIST, progression free survival (PFS) according to RECIST, overall Survival (OS), EGFR Mutational status of tumour tissue both activating and resistance EGFR mutations analysis and the association between the Veristrat assay (Biodesix) and both PFS and OS will be assessed.

Study design:
It concerns an open label, phase II, multicentre, single arm study.

Study population:
The study will recruit male or female patients aged 18 years or over with histologically confirmed, locally advanced or metastatic (stage IIIB/IV) NSCLC eligible for gefitinib re-challenge treatment who have had a documented complete (CR) or partial response (PR) or stable disease (SD) $\geq$12 weeks as the best response to their previous EGFR-TKI treatment followed by subsequent anti-cancer therapy (excluding EGFR-TKIs).

Start date:
February 2014

Total:
92 patients

Study Coordinator:
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Centraal Data Management:
NVALT Data Center, Amsterdam