Alliance A081105: Randomized Double Blind Observation Controlled Study of Erlotinib or Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)

Ramaswamy Govindan

Washington University

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Rationale

Post operative platinum doublet therapy improves overall survival in patients with completely resected stage II-III NSCLC. However, nearly 30%-50% of patients relapse despite receiving adjuvant chemotherapy.

Activating mutations in EGFR is present malignant cells in 10%-15% of patients with NSCLC. EGFR tyrosine kinase inhibitors (TKIs) have been shown to be more effective than chemo-therapy in patients with meta-static EGFR mutant NSCLC. EGFR TK inhibitors have been shown to be reasonably well tolerated with skin rash and diarrhea being the most common side effects.

The proposed study will evaluate the role of erlotinib, an EGFR TKI, in patients with stage I-III completely resected EGFR mutant NSCLC after standard post operative therapy. Patients will be randomized to observation or treatment with erlotinib for two years.

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Objective

Primary

- To assess whether adjuvant therapy with erlotinib will result in improved overall survival (OS) over observation for patients with completely resected stage IB (≥4 cm)-IIIA EGFR mutant NSCLC (confirmed centrally) following complete resection and standard post-operative therapy.

Secondary

- To assess whether adjuvant therapy with erlotinib will result in improved disease free survival (DFS) over observation for patients with completely resected stage IB (≥4 cm)-IIIA EGFR mutant NSCLC (confirmed centrally) following complete resection and standard post-operative therapy, both overall and within the stage subgroups: IB and II/IIIA.
- To evaluate the safety profile of erlotinib in the adjuvant setting.
- To assess whether adjuvant therapy with erlotinib will result in improved DFS rate at 2 years, and OS rate at 5 and 10 years over observation for patients with completely resected stage IB (≥ 4cm)-IIIA EGFR mutant NSCLC (confirmed centrally) following complete resection and standard post-operative therapy, both overall and within the stage subgroups: IB and II/IIIA.
- To assess the primary and secondary objectives in all randomized patients, regardless of central confirmation of the EGFR mutant status.

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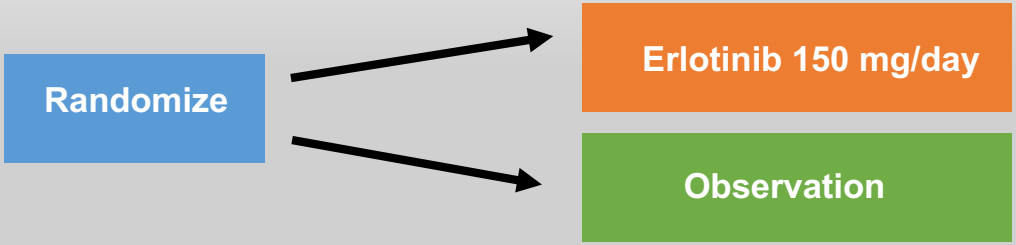
Study Schema

1 Cycle = 21 days



Patients will receive erlotinib/observation at 150 mg/day for up to 2 years.
Treatment will be discontinued at disease progression or excessive toxicity.

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Treatment Plan

Protocol treatment is to begin within 14 days following registration. For questions regarding treatment, please see the study contacts.

Patients will be randomized to one of the following 2 arms:

- Treat with erlotinib at 150 mg orally once daily for up to 2 years or until disease progression or excessive toxicity. One cycle = 21 days.
- Observation

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Key Eligibility Criteria

Inclusion Criteria

- Previously registered to A151216 with a result of EGFR exon 19 deletion or L858R mutation
- Completely resected stage IB (≥ 4 cm), II or IIIA non-squamous NSCLC with negative margins
- Complete recovery from surgery and standard post-operative therapy (if applicable)
- Age ≥18 years
- ECOG Performance Status 0-1
- No prior or concurrent malignancies within 5 years, except non-melanoma skin carcinoma or in situ carcinomas
- Non-pregnant and non-lactating
- No history of cornea abnormalities

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