Cancer Research Consortium of West Michigan
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FAST FACTS

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

NCI-supplied agent: Erlotinib

Eligibility Criteria

1. Previously registered to A151216, with the result of lung cancer harboring an EGFR exon 19 deletion or L858R mutation. The testing must have been performed by one of the following criteria:

   a) Patient registered to A151216 and the assessment performed centrally by the protocol specified laboratory.
   b) By a local CLIA certified laboratory. The report must indicate the result as well as the CLIA number of the laboratory that performed the assay. These patients will also have been registered to A151216, but can be enrolled on A081105 regardless of the central lab results.

   Patients with known resistant mutations in the EGFR TK domain (T790M) are not eligible.
   Patients that are both *EGFR* mutant and ALK rearrangements will be registered to A081105.

2. Completely resected stage IB (≥4 cm), II or IIIA non-squamous NSCLC with negative margins. Patients may not have received neoadjuvant therapy (chemo- or radio-therapy) for this lung cancer.

3. Complete recovery from surgery and standard post-operative therapy (if required). Patients must be completely recovered from surgery at the time of randomization; the minimum time requirement between date of surgery and randomization must be at least 28 days, the maximum time requirement between surgery and randomization must be 90 days if no adjuvant chemotherapy was administered, 180 days if adjuvant chemotherapy was administered, and 240 days if adjuvant chemotherapy and radiation therapy was administered.

4. Age ≥18 years.

5. ECOG Performance Status 0-1.

6. No locally advanced or metastatic cancer requiring systemic therapy within 5 years prior to registration. No secondary primary lung cancer diagnosed concurrently or within 2 years prior to registration..

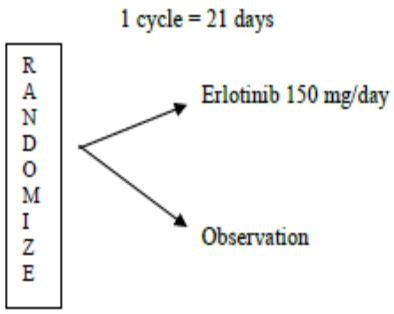
7. Non-pregnant and non-lactating.

8. No history of cornea abnormalities.

9. Required Initial Laboratory Values

Granulocytes ≥ 1,500/µl	Platelets ≥ 100,000/µl
SGOT ≤ 1.5 x ULN	Total bilirubin ≤1.5 x ULN
Serum Creatinine ≤ 1.5 x ULN	

Schema



Treatment

- **Experimental: Arm I** (erlotinib hydrochloride)
  Patients receive erlotinib hydrochloride PO QD on days 1-21. Treatment repeats every 21 days for up to 2 years

- **Placebo Comparator: Arm II** (placebo)
  Patients receive placebo PO QD on days 1-21. Treatment repeats every 21 days for up to 2 years

Pre-Study Parameters (refer to section 5)

- Physical Examination, weight, BSA, Performance Status
- Pregnancy test, Toxicity Assessment, CBC and CMP, Chest CT scan (including adrenals)