Phase I Study of Concurrent Whole Brain Radiotherapy and Erlotinib for Multiple Brain Metastases from Non-Small-Cell Lung Cancer.

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PURPOSE: Erlotinib has shown activity in patients with brain metastases from non-small-cell lung cancer. The present dose-escalation Phase I trial evaluated the toxicity of whole brain radiotherapy (WBRT) with concurrent and maintenance erlotinib in this patient group.

METHODS AND MATERIALS: Erlotinib (Cohort 1, 100 mg/d; Cohort 2, 150 mg/d) was started 1 week before, and continued during, WBRT (30 Gy in 10 fractions). Maintenance erlotinib (150 mg/d) was continued until unacceptable toxicity or disease progression.

RESULTS: A total of 11 patients completed WBRT, 4 in Cohort 1 and 7 in Cohort 2. The median duration of erlotinib treatment was 83 days. No treatment-related neurotoxicity was observed. No treatment-related Grade 3 or greater toxicity occurred in Cohort 1. In Cohort 2, 1 patient developed a Grade 3 acneiform rash and 1 patient had Grade 3 fatigue. Two patients in Cohort 2 developed erlotinib-related interstitial lung disease, contributing to death during maintenance therapy. The median overall survival and interval to progression was 133 and 141 days, respectively. Six patients developed extracranial progression; only 1 patient had intracranial progression. In 7 patients with follow-up neuroimaging at 3 months, 5 had a partial response and 2 had stable disease. CONCLUSION: WBRT with concurrent erlotinib is well tolerated in patients with brain metastases from non-small-cell lung cancer. The suggestion of a high intracranial disease control rate warrants additional study.

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