Phase I/II study of oral erlotinib for treatment of relapsed/refractory glioblastoma multiforme and anaplastic astrocytoma.


Department of Neurological Surgery, Weill Cornell Medical College of Cornell University, New York, NY 10021, USA.

Abstract

We evaluated the safety and survival benefits of orally administered erlotinib monotherapy for patients with relapsed/refractory glioblastoma multiforme (GBM) or anaplastic astrocytoma (AA). A dose escalation schedule was administered with a starting dose of 150 mg/day for the first cycle (28 days), followed by 100 mg twice daily for 14 days, and 150 mg twice daily for another 14 days. Assuming no dose limiting toxicities were observed, dosage was maintained at 150 mg BID for 10 more cycles. Disease and tumor responses were assessed after every other cycle; toxicity assessments were conducted for a minimum of 10 weeks. Patients discontinued use of enzyme-inducing anticonvulsants (EIAED) and started non-EIAEDs. Patients with previous erlotinib exposure were ineligible. Eleven patients were enrolled: 8 (73%) GBM; 3 (27%) AA. Adverse events limited study accrual, originally intended to accrue 43 patients. Nine patients (90%) experienced rash within the first 2 cycles: 7 (64%) within cycle 1; 6 (60%) reported diarrhea within the first 2 cycles. Median progression-free survival (PFS) and overall survival (OS) was 1.9 months and 6.9 months. All patients showed disease progression while on the drug. Despite the sample size, the toxicity of erlotinib supersedes any marginal benefit it as a monotherapy for relapsed/refractory GBM/AA.

PMID: 22946346 [PubMed - indexed for MEDLINE]

Publication Types, MeSH Terms, Substances

LinkOut - more resources