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### Phase III study of enzastaurin compared with lomustine in the treatment of recurrent intracranial glioblastoma.

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**PURPOSE:** This phase III open-label study compared the efficacy and safety of enzastaurin versus lomustine in patients with recurrent glioblastoma (WHO grade 4). **PATIENTS AND METHODS:** Patients were randomly assigned 2:1 to receive 6-week cycles of enzastaurin 500 mg/d (1,125-mg loading dose, day 1) or lomustine (100 to 130 mg/m<sup>2</sup>, day 1). Assuming a 45% improvement in progression-free survival (PFS), 397 patients were required to provide 80% power to achieve statistical significance at a one-sided level of .025. **RESULTS:** Enrollment was terminated at 266 patients (enzastaurin, n = 174; lomustine, n = 92) after a planned interim analysis for futility. Patient characteristics were balanced between arms. Median PFS (1.5 v 1.6 months; hazard ratio [HR] = 1.28; 95% CI, 0.97 to 1.70), overall survival (6.6 v 7.1 months; HR = 1.20; 95% CI, 0.88 to 1.65), and 6-month PFS rate (P = .13) did not differ significantly between enzastaurin and lomustine, respectively. Stable disease occurred in 38.5% and 35.9% of patients and objective response occurred in 2.9% and 4.3% of patients, respectively. Time to deterioration of physical and functional well-being and symptoms did not differ between arms (HR = 1.12; P = .54). Four patients discontinued enzastaurin because of drug-related serious adverse events (AEs). Eleven patients treated with enzastaurin died on study (four because of AEs; one was drug-related). All four deaths that occurred in patients receiving lomustine were disease-related. Grade 3 to 4 hematologic toxicities were significantly higher with lomustine (46 events) than with enzastaurin (one event; P < or = .001). **CONCLUSION:** Enzastaurin was well tolerated and had a better hematologic toxicity profile but did not have superior efficacy compared with lomustine in patients with recurrent glioblastoma.

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