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Clinical Investigations

Phase II trial of irinotecan and thalidomide in adults with recurrent glioblastoma multiforme

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Abstract

This phase II study aimed at determining the efficacy and safety of irinotecan combined with thalidomide in adults with recurrent glioblastoma multiforme (GBM) not taking enzyme-inducing anticonvulsants (EIACs). Adult patients (≥ 18 years) with recurrent GBM with up to three relapses following surgery and radiation therapy were eligible for this trial. The primary end point was rate of progression-free survival at 6 months (PFS-6); secondary end points were response rate, overall survival, and toxicity. Patients were treated in 6-week cycles with 125 mg/m² irinotecan weekly for 4 weeks followed by 2 weeks off treatment and 100 mg of thalidomide daily increased as tolerated to 400 mg/day. Of 32 evaluable patients,

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8 (25%) were alive and progression free at 6 months. The median PFS was 13 weeks. One patient experienced a complete response, one a partial response, and 19 stable disease. Median overall survival time from entry into the study was 36 weeks, and the 1-year survival rate was 34%. Adverse events (grade 3 or 4) included diarrhea, abdominal cramps, lymphopenia, neutropenia, and fatigue. Two of the four deaths that occurred were possibly due to treatment-related toxicity. The combination of irinotecan, a cytotoxic agent, and thalidomide, an antiangiogenic agent, shows promising activity against recurrent GBM in patients not receiving EIACs and warrants further study. The results also provide support for similar strategies using combination therapies with newer targeted antiangiogenic agents to generate effective therapies against malignant gliomas.

Key Words: angiogenesis, combination chemotherapy, glioblastoma multiforme, progression-free survival

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