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Randomized phase II study of cilengitide, an integrin-targeting arginine-glycine-aspartic acid peptide, in recurrent glioblastoma multiforme.

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PURPOSE: Cilengitide, an inhibitor of alphavbeta3 and alphavbeta5 integrin receptors, demonstrated minimal toxicity and durable activity across a wide range of doses administered to adults with recurrent glioblastoma multiforme (GBM) in a prior phase I study. The current multicenter phase II study was conducted to evaluate the activity and safety of cilengitide in GBM patients at first recurrence. PATIENTS AND METHODS: Eligible patients were randomly assigned to receive either 500 or 2,000 mg of cilengitide twice weekly on a continuous basis. Patients were assessed every 4 weeks. The primary end point was 6-month progression-free survival (PFS) rate. Secondary end points included PFS, overall survival (OS), and radiographic response, as well as quality-of-life and pharmacokinetic assessments. RESULTS: Eighty-one patients were enrolled, including 41 on the 500-mg arm and 40 on the 2,000-mg arm. The safety profile of cilengitide was excellent, with no significant reproducible toxicities observed on either arm. Antitumor activity was observed in both treatment cohorts but trended more favorably among patients treated with 2,000 mg, including a 6-month PFS of 15% and a median OS of 9.9 months. CONCLUSION: Cilengitide monotherapy is well tolerated and exhibits modest antitumor activity among recurrent GBM patients. Additional studies integrating cilengitide into combinatorial regimens for GBM are warranted.

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