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### **Extended-schedule dose-dense temozolomide in refractory gliomas.**

[Berrocal A](#), [Perez Segura P](#), [Gil M](#), [Balaña C](#), [Garcia Lopez J](#), [Yaya R](#), [Rodríguez J](#), [Reynes G](#), [Gallego O](#), [Iglesias L](#); [GENOM Cooperative Group](#).

Servicio de Oncología Medica, Consorcio Hospital General Universitario de Valencia, Avda Tres Cruces S/N, 46006, Valencia, Spain, berrocal\_alf@gva.es.

This multicenter phase II study conducted by the Spanish Neuro-Oncology Group evaluated the activity of an extended, dose-dense temozolomide regimen in patients with temozolomide-refractory malignant glioma. Adult patients (at least 18 years of age) with WHO grade III or IV glioma and a Karnofsky Performance Status of 60 or higher were treated with temozolomide (85 mg/m<sup>2</sup>/day) for 21 consecutive days every 28-day cycle until disease progression or unacceptable toxicity. All patients had developed progressive disease either during or less than 3 months after completing previous temozolomide treatment. Forty-seven patients were treated with a median of 2 (range, 1-13) cycles of temozolomide. Before study entry, patients had received a median of 6 cycles of temozolomide: 39 (83%) as part of initial therapy and 23 (49%) as second-line therapy. Three patients (6.4%) had a partial response with durations of 8.0, 3.5, and 3.2 months; 15 patients (31.9%) had stable disease with a median duration of 2.1 months, including 2 patients with stable disease (SD) for greater than 6 months (14 and 16 months). Median time to progression was 2 months, and median overall survival from study entry was 5.1 months. The 6-month progression-free survival rate was 16.7%. The most common hematologic toxicities were lymphopenia, thrombocytopenia, and leukopenia. Lymphopenia occurred in 83% of patients and was grade 3 in 28%, but no opportunistic infections occurred. In conclusion, this extended dose-dense schedule of temozolomide appears to have modest activity in patients refractory to previous treatment with temozolomide and is associated with manageable toxicity.

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