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1: Br J Cancer. 2003 Jul 21;89(2):248-51.

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BJC British Journal of Cancer

Phase I study of temozolamide (TMZ) combined with procarbazine (PCB) in patients with gliomas.

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Temozolomide (TMZ) is an oral alkylating agent with a good safety profile and proven efficacy in the treatment of malignant glioma. Procarbazine (PCB) has been used for treating gliomas for many years and here both agents were combined in the treatment. This phase I study was designed to evaluate the efficacy and safety of TMZ alone (course 1) and TMZ in combination with PCB in subsequent courses in chemotherapy-naive patients with malignant glioma. Patients with anaplastic astrocytoma (AA), glioblastoma multiforme (GBM) and low-grade glioma were treated with TMZ 200 mg m(-2) on days 1-5 on a 28-day cycle for course 1. Beginning with course 2, cohorts of patients received TMZ at full dose with escalating doses of PCB (50/75/100/125 mg m(-2) days 1-5 given 1 h prior to TMZ). A total of 28 patients were enrolled with three patients each at dose level 1 and 2, 16 patients at dose level 3 and six patients at dose level 4 received 182+ cycles of treatment and were included in this analysis. In all, 16 patients had GBM, seven patients had AA, five had grade 1 or 2 glioma and the median age was 47 years. The patients had received prior surgery and radiotherapy. Responses were seen at all dose levels. Overall, there were 10 (36%) responses lasting from 2 to 17+ months. Treatment was generally well tolerated with few grade 3 or 4 toxicities, except at dose level 4, where four patients had grade 3/4 had thrombocytopaenia at this dose and several patients had moderate-to-severe lethargy. TMZ 200 mg m(-2) and PCB 100 mg m(-2) were well tolerated on a daily 5 x and four weekly cycle in patients with malignant glioma and clearly had antitumour activity.

Publication Types:
- Clinical Trial
- Clinical Trial, Phase I

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