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Temozolomide in combination with docetaxel in patients with advanced melanoma: a phase II study of the Hellenic Cooperative Oncology Group.

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Source

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Abstract

PURPOSE:

Temozolomide is a novel oral alkylating agent that is effective against melanoma. Moreover, temozolomide readily crosses the blood-brain barrier and may consequently be effective in patients with brain metastases. This phase II study was performed to assess the efficacy and safety of the combination regimen of temozolomide and docetaxel in patients with advanced metastatic melanoma.

PATIENTS AND METHODS:

Sixty-five patients with metastatic melanoma were enrolled. Treatment consisted of intravenous docetaxel (80 mg/m(2)) on day 1 and oral temozolomide (150 mg/m(2)) on days 1 to 5, every 4 weeks, for a maximum of six cycles.

RESULTS:

Sixty-two patients were eligible for the efficacy and safety analysis. Seventeen patients (27%) achieved an objective response, including five complete (8%) and 12 partial responses (19%). Median response duration was 9.5 months. Among responders, median time to progression (TTP) was 11.2 months and median overall survival (OS) was 16 months. For all treated patients, the median TTP was 4 months and median OS was 11 months. Three (38%) of eight patients who presented with brain metastases had a partial response for 5, 6, and 12 months. Of 52 patients who did not have brain involvement at presentation, only four (8%) developed brain metastases at a median follow-up of 14 months. Myelosuppression was the primary toxicity.

CONCLUSION:

The combination of temozolomide and docetaxel was effective and well tolerated as first-line treatment for patients with advanced metastatic melanoma and demonstrated encouraging antitumor activity against brain metastases.