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Central nervous system failure in melanoma patients: results of a randomised, multicentre phase 3 study of temozolomide- and dacarbazine- based regimens.

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Abstract

BACKGROUND: This study compared the central nervous system (CNS) metastasis incidence between a temozolomide- and a dacarbazine-based regimen in untreated stage IV melanoma patients.

METHODS: A total of 150 patients were randomly assigned to receive either oral temozolomide (200 mg m⁻²) per day; days 1-5) or intravenous dacarbazine (800 mg m⁻²; day 1), in combination with intravenous cisplatin (75 mg m⁻²; day 1) and subcutaneous interleukin-2 (3 MU twice daily; days 9-18), every 28 days (CTI and CDI).

RESULTS: A total of 149 patients were eligible for an intention-to-treat analysis (CTI: n=74, CDI: n=75). The 1-year cumulative CNS incidence failure was 20.6% for CTI and 31.1% for CDI (P=0.22). In all 24 patients in CTI (32%) and 34 (45%) in CDI developed CNS metastases; 31 patients died of early systemic progression, before CNS evaluation. Median survival time was 8.4 months in the CTI and 8.7 in the CDI arm; in patients with CNS metastases the median survival time was 13.5 months in the CTI and 11.5 in the CDI arm. No difference in toxicity was observed between the two arms.

CONCLUSION: The incidence of CNS failures in metastatic melanoma was not significantly reduced and the clinical course was not modified substituting a dacarbazine-based regimen with a temozolomide-based regimen. Patients who developed CNS metastases did not have a worse prognosis than patients progressing in other sites and should not be excluded from new investigational studies.

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