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Phase I/II study of (131)I-MIBG with vincristine and 5 days of irinotecan for advanced neuroblastoma.

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Abstract

BACKGROUND: (131)I-metaiodobenzylguanidine (MIBG) is an active radiopharmaceutical in neuroblastoma. A previous study demonstrated that MIBG could be combined with vincristine and prolonged irinotecan, although 25% of first courses had grade 3 diarrhoea. The current phase I/II study evaluated MIBG with vincristine and 5 days of higher-dose irinotecan.

METHODS: Patients 1-30 years old with advanced neuroblastoma were eligible. Patients received cefixime on days -1 to +6, irinotecan (50 mg m(-2) per dose IV) on days 0-4, vincristine (2 mg m(-2)) on day 0, MIBG (555 or 666 MBq kg(-1)) on day 1, and peripheral blood stem cells on day 13. UGT1A1 genotyping was performed in consenting patients.

RESULTS: Thirty-two patients (12 phase I ; 20 phase II) received 42 courses. No dose-limiting toxicities were seen during dose escalation and the recommended administered activity was 666 MBq kg(-1). Myelosuppression and diarrhoea were the most common toxicities, with grade 3 diarrhoea in 6% of first courses. Patients homozygous for UGT1A1*28 had more grade 4 thrombocytopenia (80% vs 37%; P=0.14). Responses (five complete and four partial) occurred in 9 out of 32 (28%) patients.

CONCLUSIONS: MIBG (666 MBq kg(-1)) with vincristine and this irinotecan schedule is tolerable and active, with less severe diarrhoea compared with a regimen using more protracted irinotecan.

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