Randomized phase III study of 1 month versus 1 year of adjuvant high-dose interferon alfa-2b in patients with resected high-risk melanoma.

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Source

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Abstract

PURPOSE:

A high-dose interferon alfa (IFN-alpha) regimen as reported in E1684 was unique for the incorporation of an induction phase of maximally tolerated dosages of intravenous (IV) therapy for the initial 4 weeks. This is the only trial that has shown prolongation of overall survival and relapse-free survival (RFS) in comparison with observation. Analysis of the hazard curves for RFS and overall survival (OS) in E1684 revealed separation of the high-dose and observation arms, suggesting that the induction phase may represent a critical component of this regimen, although this has not been tested prospectively.

PATIENTS AND METHODS:

We conducted a prospective randomized study of IV induction therapy versus a full year of high-dose IFN, with primary end points of RFS and OS for patients with stage IIB, IIC, and III melanoma, within 56 days of curative surgery. Patients were randomly assigned to receive IFN-alpha-2b 15 x 10(6) U/m2 IV x 5/7 days weekly x 4 weeks (arm A) versus the same regimen followed by IFN-alpha-2b 10 x 10(6) U (flat dose) administered subcutaneously three times a week for 48 weeks (arm B).

RESULTS:

Between 1998 and 2004, 364 patients were enrolled (353 eligible: arm A, n = 177; arm B, n = 176). At a median follow-up of 63 months (95% CI, 58.1 to 67.7), the median RFS was 24.1 months versus 27.9 months (P = .9) and the median OS was 64.4 months versus 65.3 months (P = .49). Patients in arm B had more grade 1 to 2 hepatotoxicity, nausea/vomiting, alopecia, and neurologic toxicity.

CONCLUSION:

There were no significant differences in OS and RFS between the regimens of 1 month and 1 year of treatment.

Comment in

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