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Title
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Permalink
https://escholarship.org/uc/item/0vw6c1wq

Journal
Journal of the National Cancer Institute, 82(12)

ISSN
0027-8874

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Publication Date
1990-06-20

DOI
10.1093/jnci/82.12.1071-a

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Recombinant Human Interferon γ: Adverse Effects in High-risk Stage I and II Cutaneous Malignant Melanoma

Data from the Southwest Oncology Group (SWOG) study 8642 indicate that recombinant human interferon γ (rIFN-γ) may have an adverse effect in patients with stage I and II (high risk) cutaneous malignant melanoma. We, therefore, have discontinued the clinical trial.

This study was a stratified, randomized phase III adjuvant trial. After excision of the primary lesion, patients were randomly selected for observation or for treatment with rIFN-γ at a dose of 0.2 mg/day given subcutaneously for 1 year. Accrual to the study was rapid.

The first analysis, in October 1989, suggested that rIFN-γ was unlikely to have a beneficial effect, and an accelerated schedule of interim analysis was initiated. At that time, the study was temporarily closed.

A reanalysis in April 1990 effectively ruled out the possibility that rIFN-γ can produce a 50% or greater improvement in disease-free survival ($P = .002$). We cannot conclude that disease-free survival is significantly worse in the rIFN-γ group. However, in patients with stage II disease, the number of relapses or deaths and the median time to relapse suggest that rIFN-γ may be having an adverse effect. Of 58 patients treated with rIFN-γ, 34 had relapse or died; of 66 who were observed, 25 had relapse or died. The median time to relapse was 9.5 months for treated patients and 15.3 months for patients who were observed. Additionally, there have been 21 deaths in the rIFN-γ group with stage II disease (median survival time, 22.9 mo); only 10 deaths have been seen in the observation group, and the median survival time has not been reached. Among patients with stage I disease, the rIFN-γ group has more relapses and deaths than the control group, but the numbers of these events are still small.

The Data Monitoring Committee for this study has, therefore, taken the following steps: (*a*) the trial has been permanently closed, and (*b*) the present interim results have been made available to Canadian investigators using rIFN-γ for a similar trial and to SWOG investigators who have patients still receiving interferon. These results are preliminary but are of sufficient concern that we prepared this letter to inform the oncology community. A full report will follow at an appropriate time.

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