



Update

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AIDS patients with Kaposi's sarcoma may benefit from treatment with alpha interferon, according to a study published this week in the journal Lancet by scientists at the National Institute of Allergy and Infectious Diseases. Dr. H. Clifford Lane, NIAID, and his colleagues have shown that alpha interferon has both anti-retroviral and anti-tumor effects in patients with early AIDS and Kaposi's sarcoma, a systemic cancer that primarily affects AIDS patients.

Approval of alpha interferon for the treatment of AIDS-associated Kaposi's sarcoma was announced at the beginning of this week by the Food and Drug Administration. The approval was based in part on data from Dr. Lane's study, which determined that the drug is most effective in those patients whose immune systems are less damaged by infection with the human immunodeficiency virus (HIV), the cause of AIDS.

Patients who experience the most beneficial effects of high doses of alpha interferon are those who have CD4 (T4 helper) cell counts of more than 200 and who have not had AIDS-related opportunistic infections, Dr. Lane found. HIV seeks out and destroys CD4 cells, which are essential to the body's immune defenses.

Alpha interferon, a naturally occurring protein produced in quantity through recombinant technology, has anti-tumor, immunomodulatory, and antiviral activities. It has been studied for at least 6 years in AIDS patients as a treatment for Kaposi's sarcoma. While tumor regressions have been seen in between 20 and 67 percent of the patients, scientists have not known whether the results reflect an anti-tumor effect alone, whether alpha interferon acts by boosting the immune system, or whether the drug acts against HIV itself.

To assess the anti-retroviral effects of alpha interferon, Dr. Lane conducted an open trial using the highest tolerable doses of the drug. Twenty-one patients with AIDS and Kaposi's sarcoma received daily subcutaneous injections of the drug, beginning at 35 million units per day and reduced as necessary to manage toxicity. Adverse reactions to the drug include flu-like symptoms and, less commonly, more severe side effects. After 12 weeks of treatment, Dr. Lane assessed each patient's dose regimen and made additional changes.

"The patients' responses closely correlated with their immune function, as measured by their CD4 lymphocyte counts," Dr. Lane said. Eight patients had complete or partial tumor remissions; all of the five who had complete remissions of tumors had CD4 counts of more than 400 cells per cubic millimeter in peripheral blood at the beginning of treatment.

Viral cultures and tests of p24 antigen, which measure HIV activity, changed from positive to negative in several patients. The anti-HIV effect was seen only in those patients with the best immune function who received long-term, high-dose therapy. When the treatment had to be withdrawn because of side effects, as happened in 9 of the 21 patients, or the dosage had to be reduced, virus production returned rapidly.

"Our results show that alpha interferon has a promising anti-HIV effect and can improve the quality of life for certain patients with AIDS," Dr. Lane said. The study, he added, has provided the scientific rationale for additional studies of alpha interferon in patients with early stages of HIV infection. Volunteers at early stages of HIV infection are now being sought for an NIAID study comparing treatment with alpha interferon plus zidovudine (commonly known as AZT) to treatment with zidovudine or alpha interferon alone. Interested individuals should call Victoria Davey, R.N., at (301) 496-7196.

The study, reported in the November 26, 1988 Lancet, was conducted by H. Clifford Lane, M.D., Judith Feinberg, M.D., Victoria Davey, R.N., Lawrence Deyton, M.D., Betsey Herpin, R.N., Robert Walker, M.D., Julia A. Metcalf, R.N., and Anthony S. Fauci, M.D., NIAID, National Institutes of Health (NIH), Bethesda, Md.; Michael Baseler, (degree?) Program Resources, Inc., Frederick, Md.; Jody Manischewitz, (degree?) and Gerald Quinnan, M.D., Food and Drug Administration; Henry Masur, M.D., and Joseph Kovacs, M.D., Clinical Center, NIH; and Norman Salzman, M.D., Georgetown University, Washington, D.C.