



National Institute of Allergy and Infectious Diseases

Update

FOR RELEASE
June 13, 1988

PUBLIC HEALTH SERVICE
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NIAID SCIENTISTS REPORT NEW RESULTS OF AIDS VACCINE STUDY

Scientists at the National Institute of Allergy and Infectious Diseases (NIAID) have reported new results from a continuing study of the first experimental AIDS vaccine to be tested in humans in the United States.

Dr. H. Clifford Lane, Deputy Clinical Director, NIAID, speaking at the Fourth International Conference on AIDS in Stockholm, said that 20 volunteers have developed an immune response to the vaccine. He presented data on 60 volunteers who have been inoculated in a trial using escalating doses of a recombinant AIDS vaccine manufactured by MicroGeneSys, Inc., a biopharmaceutical firm in West Haven, Connecticut. The vaccine consists of purified envelope protein (gp160) derived from the genetic material of the human immunodeficiency virus (HIV), the cause of AIDS. Participants in the study are homosexual and bisexual men who are at low risk of HIV infection.

The participants were divided into four groups; the first group of volunteers received 10 micrograms of gp160 and the dose was doubled for each successive group. Two-thirds of each group received a booster dose (either 50 percent or 100 percent of the primary dose) one month later.

The Western blot test is being used to examine blood specimens, taken weekly, for antibody responses to the various doses of the vaccine. This test can detect the specific HIV proteins against which an individual's immune system has produced antibodies.

Of the 16 volunteers who were immunized with 40 micrograms of the vaccine, 10 showed an antibody response to gp160. Four of the 5 persons who received primary immunizations and no boosters showed antibodies by 8 weeks. Six out of the 10 persons who received a primary dose and a booster at one month also showed antibodies by 8 weeks. Of the 15 volunteers who received 80 micrograms of the vaccine, 10 have developed antibodies thus far.

Local reactions (tenderness, redness, and swelling), flu-like symptoms, and fever of up to 24 hours duration, common in the administration of any vaccine, occurred in some volunteers. No serious toxicities attributable to the vaccine have been seen.

The investigators stated that immunization with gp160 appears safe during short-term followup with initial doses up to 80 micrograms. The study is continuing, and volunteers are now being recruited to receive 160 micrograms of the vaccine. Completion of this Phase I/II study will determine the optimal dosing regimen and the nature of the antibody and "cell-mediated" immune responses to this vaccine.

The study is being conducted at the Clinical Center, the research hospital of the National Institutes of Health, Bethesda, Maryland. NIAID is sponsoring an additional clinical study of this vaccine in volunteers recruited at its six Vaccine Evaluation Units, based at U. S. universities. No results have been reported from that study.

Dr. Lane also reported on the results of recent tests run on blood samples of volunteers who did not qualify for inclusion in the study because of aberrant Western blot test results. Prior to enrollment in the Bethesda study, all volunteers underwent a number of tests to exclude anyone with prior HIV infection. Their blood was tested for antibodies to HIV, using the ELISA (the antibody test used commonly to screen donated blood) and the Western blot (which measures antibodies to specific viral proteins). Their blood was also tested for p24 antigen (HIV core protein), which often shows up prior to antibody production. Finally, co-cultivation was attempted, in which normal lymphocytes are mixed with the volunteer's blood to see whether any virus present will infect the normal cells.

Among the volunteers screened for the study, 53 out of 177, or 30 percent, were found

to have reactivity with one or more virus-specific or non-specific bands by Western blot despite having a negative ELISA, negative p24 antigen, and negative co-culture. Although the investigators had no evidence at the time that this reactivity represented true HIV infection, they did not enter these volunteers into the study.

Using a new, experimental test--polymerase chain reaction (PCR), which makes use of a technique called gene amplification--the investigators subsequently found that 3 out of 20 volunteers with abnormal reactivity patterns had HIV genetic material integrated into their lymphocytes. The PCR tests, which are being conducted in collaboration with Dr. John J. Sninsky of Cetus Corporation, Emeryville, Calif., are also being used to test blood samples of the volunteers who received the vaccine.

Other collaborators on the study include Anthony S. Fauci, M.D., Malcolm A. Martin, M.D., Lawrence Deyton, M.D., Thomas M. Folks, Ph.D., Margaret Megill, and Julie A. Metcalf, NIAID; Joseph A. Kovacs, M.D., and Henry Masur, M.D., Clinical Center, National Institutes of Health; Franklin Volvovitz, Mark A. Cochran, Ph.D., and Gale Smith, Ph.D., MicroGeneSys, Inc., West Haven, Conn.; Michael Baselar, Program Resources, Inc., Frederick, Md.; and Norman P. Salzman, Ph.D., and M. B. Vasudevachari, Ph.D., Georgetown University, Washington, D.C.

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