National Institute of Allergy and Infectious Diseases

Update

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NIAID SCIENTISTS REPORT FIRST RESULTS OF U.S. AIDS VACCINE STUDY

Volunteers in an ongoing study of the first experimental AIDS vaccine to be tested in humans in the United States have developed an immune response to the vaccine, according to scientists at the National Institute of Allergy and Infectious Diseases (NIAID).

The vaccine, which consists of purified envelope protein (gp160) derived from the genetic material of the human immunodeficiency virus (HIV), the cause of AIDS, is manufactured by MicroGeneSys, Inc., a biopharmaceutical firm in West Haven, Conn. The study, which is designed to evaluate the vaccine's safety and ability to produce an immune response, and to determine proper dosage, is being conducted at the Clinical Center, National Institutes of Health. Participants in the study are homosexual and bisexual men who are at low risk of HIV infection.

Fifty-nine volunteers, all of whom underwent a number of tests to exclude anyone with prior HIV infection, have been immunized with the vaccine. The first group of 14 participants received 10 micrograms of gp160, and the dose was doubled for each successive group of 15. Two-thirds of each group were scheduled to receive a booster dose (either 50 percent or 100 percent of the primary dose) one month later. The Western blot test is used to test blood specimens, taken weekly, for antibody responses to the various doses. This test can detect the specific HIV proteins against which an individual's immune system has reacted.

Of 15 volunteers immunized with 40 micrograms, 6 showed an antibody response to gp160. Two of the 5 persons who received primary immunizations and no boosters showed antibodies

by 8 weeks. Four out of the 10 persons who received a primary dose and a booster at one month also showed antibodies by 8 weeks.

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, but 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, with volunteers scheduled to receive booster doses. 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.

NIAID is sponsoring an additional clinical study of this vaccine in volunteers recruited at its six university-based Vaccine Evaluation Units. No results have been reported from that study.

The research results were presented April 30 at the annual meeting of the American Foundation for Clinical Research, Washington, DC, by Joseph A. Kovacs, M.D., Critical Care Medicine Department, NIH Clinical Center (CC), and H. Clifford Lane, M.D., Laboratory of Immunoregulation, NIAID. Other authors included Anthony S. Fauci, M.D., Thomas M. Folks, M.D., Malcolm A. Martin, M.D., Margaret E. Megill, R.N., Lawrence R. Deyton, M.D., Richard T. Davey, Jr., M.D., and Julia A. Metcalf, NIAID; Henry Masur, M.D., CC, NIH; Norman Salzman, M.D., Georgetown University; Michael Baselar, Program Resources, Inc., Frederick, Md.; and Franklin Volvovitz, Mark A. Cochran, Ph.D., and Gale E. Smith, Ph.D., MicroGeneSys, Inc., West Haven, Conn.

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