



Update

FOR IMMEDIATE RELEASE

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VOLUNTEERS NEEDED FOR ONGOING AIDS VACCINE STUDY

Additional volunteers are being sought for the AIDS vaccine study that is underway at NIAID in Bethesda, Maryland. The study is designed to determine the best dosing regimen and the nature of the antibody and cell-mediated immune responses to this vaccine. At the recent Fourth International Conference on AIDS in Stockholm, NIAID scientists reported promising new results from this study--the first experimental AIDS vaccine to be tested in humans in the United States.

Dr. H. Clifford Lane, Deputy Clinical Director, NIAID, said that 20 volunteers had developed an immune response to the vaccine. He presented data on 60 volunteers who have already been inoculated 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 healthy homosexual and bisexual men who are at low risk of HIV infection.

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. Four of the 5 persons who received primary immunizations and no boosters developed antibodies within 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 so far. The investigators stated that immunization with gp160 appears safe during short-term followup with initial doses up to 80 micrograms.

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.

Volunteers must be healthy homosexual or bisexual men who are at low risk of HIV infection, and are able to come to NIAID once per week for the first month after vaccination, and subsequently once per month for the next year. Travel expenses for volunteers who are not local will be paid by NIH. To obtain more information or to volunteer, call 1-800-634-3027. In Connecticut, call 1-203-932-2538. Prospective volunteers may also call 1-301-496-7196.

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Dear Writers and Editors:

The first AIDS vaccine trial is progressing well; some volunteers have had an immune response to the vaccine, and there have been no serious side effects. As you can see from the enclosed Update, we are anxious to recruit more volunteers to obtain further necessary data. We hope that you will print this request to help our AIDS vaccine development efforts.

If you need more information or want to interview a scientist about the study, please contact my office at the number above.

Sincerely,

Patricia S. Randall

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