

Open Clinical Trials for HIV/AIDS Treatments

Mike Donnelly

Below is a partial listing of currently enrolling U.S. clinical trials gathered from various sources. Two of the main clinical trial resource centers have undergone significant changes.

At the end of June 2002 HIV InSite's Trials Search database of HIV/AIDS clinical trials was replaced with TrialScope, a listing of clinical trial sites with contact information for HIV/AIDS clinical research organizations in the U.S. TrialScope allows online users to search by country, state, and city, or by type of trial. TrialScope is available at <http://hivinsite.ucsf.edu/tsearch>. HIV InSite, a program of the University of California at San Francisco (UCSF), will no longer publish the *Guide to HIV Clinical Trials in California*. The Trials Search database may become available in the future pending its transfer to a community-based organization.

In May 2002 the AIDS Clinical Trials Information Service (ACTIS) announced that it will no longer maintain its own database of clinical trials. Instead, ACTIS will allow users to search for HIV/AIDS-related studies listed at ClinicalTrials.gov, a clinical trial database for all diseases supported by the National Institutes for Health (NIH). The ClinicalTrials.gov database will be accessible at both www.actis.org and www.clinicaltrials.gov. ACTIS information specialists will continue to be available to help locate trials and answer questions at 800-874-2572 from 12:00 pm to 5:00 pm ET (9:00 am to 2:00 pm PT) Monday through Friday.

Call the telephone numbers below for more information about specific trials and a full listing of study sites. Protocol (study) numbers, if available, are provided in parentheses at the end of each trial description.

Gene Therapy

This Phase II, multicenter, randomized, and blinded study will help determine the safety and efficacy of administering a gene transfer product to people with chronic HIV. Participants will be given granulocyte colony-stimulating factor (G-CSF) to stimulate the production of white blood cells, which then will be harvested through apheresis (removal from the blood for therapeutic purposes). The harvested cells will be genetically recombined with either a delivery gene construct or one that delivers an anti-HIV ribozyme (RNA that can alter the genetic instructions of DNA or RNA). Participants will have the altered cells reinfused and will continue taking their antiretroviral therapy (HAART) for 24 weeks. HAART then will be interrupted for four weeks, resumed for 12 weeks, and interrupted again for another 12 weeks. The primary efficacy endpoint for the study will be HIV viral load levels at 47 and 48 weeks after cell reinfusion. Eligible participants must be between 18 and 45 years of age, be taking their first or second antiretroviral regimen, and have at least 300 CD4 cells/mm³ and a viral load below 50 copies/mL for the previous six months. For more information, call Debbie Slamowitz at Stanford University (650-723-2804).

Structured Treatment Interruption

This 72-week (18-month) study will evaluate the virologic and immunologic effects of intermittent versus continuous HAART in HIV positive individuals, with the goals of suppressing viral replication, minimizing the toxicity and side effects of HAART, and reducing cost. Eligible participants will be randomized into two study groups. Participants in group one will continue taking their current antiretroviral therapy; participants in group two will stop their therapy every other week in seven-day cycles. In other words, those in group two will take therapy in a one-week on, one-week off pattern. Eligible participants must be HIV positive people 18 years of age or older who are currently on an effective antiretroviral regimen, as defined by having had an undetectable viral load for a minimum of one month and having 175 or more CD4 cells/mm³. Participants' regimens must not contain nevirapine (Viramune) or abacavir (Ziagen). Exclusion criteria include resistance to any approved anti-HIV medications, any major opportunistic illnesses (OIs), and chronic hepatitis B. Blood will be drawn at the end of an off-drug period either monthly or every other month. Virologic tests (studies of HIV) and immunologic tests (studies of the immune response to HIV) also will be done, and medications and clinical care will be provided during the study. This study takes place in Bethesda, MD. To offset costs after the first visit, travel (plane, train, automobile) will be paid for, and there will be an \$80 per night hotel allowance. (Travel arrangements must be made through the study coordinator.) For more information, contact

Diane M. Rock Kress, RN, at 301-435-8003 or 800-772-5464, ext. 58003. The study protocol may be viewed online at www.niaid.nih.gov/dir/labs/lir/hiv/haart.htm. (02-I-0013)

Immunomodulating Therapy: Z-100

This Phase I study will help determine the safety of Z-100, an experimental immunomodulator that has shown antiviral activity against HIV in the test tube. Participants will be assigned by chance to receive one of two doses of Z-100 or placebo (an inactive substance). Participants will be taught to self-administer two 1 mL injections subcutaneously (under the skin) twice weekly for eight weeks. Eligible participants must be at least 18 years of age and have at least 350 CD4 cells/mm³ and a viral load between 2,000 and 55,000 copies/mL. Study locations include Chicago (312-695-5012) and Galveston, TX (409-747-0218).

Peptide T

This Phase II, open-label study will measure the effect of Peptide T on viral load and immune function. Peptide T is an intranasal solution that is sprayed into the nose, four sprays three times daily. The procedure is like using an over-the-counter nasal spray. Eligible participants must have at least 300 CD4 cells/mm³ and a viral load between 500 and 25,000 copies/mL. Antiretroviral therapy is optional; people who have never taken or who have stopped therapy are eligible for this study. Those receiving antiretroviral treatment must have been on stable (unchanged) therapy for 12 weeks prior to study entry. For more information, contact Diane Cenko at HIV Care in San Francisco (415-353-6215 or dcenko@chw.edu).

DHEA

This is a randomized, placebo-controlled pilot study of DHEA, a hormone produced in the body. The study will evaluate how supplementing the amount of DHEA affects HIV, the immune system, hormone levels, body composition, and quality of life. Participants will be assigned by chance to take either DHEA or placebo twice daily for 12 weeks. There will be eight visits to San Francisco General Hospital for blood and urine tests, body measurements, and completion of questionnaires. Participants will receive \$25 per visit and the study medication is free of charge. Eligible participants must have a viral load below 50 copies/mL; have been on stable antiretroviral treatment for eight weeks; not have active OIs, malignancies, or severe liver disease; and not be pregnant or breast-feeding. Exclusion criteria include use of DHEA, testosterone, other anabolic steroids, corticosteroids, megestrol acetate (Megace), growth hormone, IL-2, or thalidomide in the previous eight weeks. This study is being conducted at the Community Consortium of UCSF; for more information, contact Paul Couey at 415-476-9554, ext. 15. (CC047/GCRC 664)

Natural History of HIV in Women

Several years ago the National Institute of Allergy and Infectious Diseases (NIAID) established a large-scale natural history study of women and HIV infection known as the Women's Interagency HIV Study (WIHS). WIHS was a multicenter, prospective (forward-looking) study of the natural history of HIV infection in U.S. women. The study enrolled women who were HIV positive and women who were HIV negative but at high risk for becoming HIV infected through behaviors such as intravenous (IV) drug use, having multiple sexual partners, and practicing unsafe sex. The original study sites were the Bronx/Manhattan, Brooklyn, Chicago, Los Angeles, San Francisco, and Washington, DC.

The overarching purpose of the study was to identify clinical signs of HIV infection in women, to describe the pattern and rate of immune system decline, and to examine potential cofactors that might affect disease progression. Although the study closed for a time, researchers at the University of California at San Francisco (UCSF) are once again actively recruiting for WIHS in the San Francisco Bay Area.

Eligible participants must be HIV positive or at risk (as defined above) and 18 to 30 years of age. Investigators also will look at issues affecting length of survival and quality of life for women with HIV infection. All participants will have biannual (twice yearly) examinations that include an interview, physical exam, and laboratory blood tests. For more information, call (toll-free) 866-476-5109.

Abdominal Obesity in Men: Testosterone

This prospective, placebo-controlled study will determine the safety and effectiveness of testosterone gel in reducing abdominal fat in men. All participants will be assigned at random to receive testosterone gel or placebo. Participants will apply the gel to their shoulders, arms, or abdomens, and will receive physical exams and blood tests every six weeks. Questionnaires, body measurements, rectal exams, additional blood tests, and computed tomography (CT) and DEXA (body composition) scans will be done every 12 weeks. After 24 weeks all participants will be offered testosterone gel for an additional 24 weeks. Eligible participants must be male, have a viral load below 10,000 copies/mL, and have been on stable antiretroviral therapy for at least 12 weeks prior to study entry, with plans to continue the same regimen for at least another 24 weeks. Exclusion criteria include use of testosterone, anabolic steroids, appetite stimulants, DHEA, growth hormone, or other anabolic agents within 12 weeks of study entry, and use of hydroxyurea (Hydrea) within 30 days of study entry. Study locations include Denver (303-372-5535), Honolulu (808-737-2751), Indianapolis (317-274-8456), San Diego

(619-543-8080), and San Francisco (415-514-0550 ext. 356). (A5079)

Neurological Studies

Two important clinical studies (see below) are in danger of closing due to slow accrual. These studies ask crucial questions about decreased mental function and about HIV in the cerebrospinal fluid (CSF, the fluid surrounding the brain and spinal cord) and its relationship to virus in the blood. In a letter to community advisory boards serving the AACTG (Adult AIDS Clinical Trial Group) network, Giovanni Schifitto, MD, study chair of AACTG A5090, explains the importance of this trial:

An important change in the progression of cognitive impairment is that while in the early days of the epidemic we were concerned with rapid progression to dementia (patients with dementia had a six-month median survival), we are now observing long periods of cognitive impairment without apparent improvement or worsening. However, fully functional activities cannot be expected with persistent cognitive deficits. Since HIV infection is becoming a manageable, chronic disease, we need to be attentive to cognitive function to prolong not only survival, but also quality of life.

Often the community criticizes researchers for not exploring complications of long-term use of antiretroviral therapy and HIV infection itself. These studies aim to provide answers to important questions now being asked. Please talk with a health-care provider and consider participating in these clinical trials.

Decreased Mental Function: Selegiline

This Phase II, placebo-controlled, double-blind study will examine whether the selegiline transdermal system (skin patch) is safe and effective in treating decreased mental function in people with HIV. Currently oral selegiline is approved for the treatment of Parkinson's disease. Prospective participants will undergo blood draws, lumbar punctures (spinal taps), and screening tests to determine brain function. Eligible participants will be randomized to receive patches with one of two doses of selegiline or placebo patches. Study visits will take place at weeks 4, 8, 12, 16, and 24. Visits at weeks 12 and 24 will include mental function tests and surveys; the week 24 visit will include another lumbar puncture. Participants who complete the first 24-week stage of the trial will have the option to take part in an additional 24-week, open-label stage. Participants must be at least 18 years of age and have impaired mental functioning as indicated by prestudy screening tests. There is no CD4 cell count or viral load requirement. Participants must have been on stable anti-HIV therapy for the previous eight weeks or off treatment for the previous eight weeks due to drug resistance or intolerance. Exclusion criteria include syphilis, active AIDS-defining OIs within 30 days of study

entry, use of over-the-counter diet or cold remedies within 14 days, high blood pressure, and pregnancy or breast-feeding. Study sites include Boston (617-726-3819); Buffalo, NY (716-273-2114); Chicago (312-695-5012); Honolulu (808-737-2751); Los Angeles (310-825-3594); New York City (212-305-2387, 212-420-4432, or 212-241-8748); Philadelphia (215-349-8092); Rochester, NY (716-275-2740); San Diego (619-543-8080); San Francisco (415-514-0550 ext. 362); Seattle (206-731-8877); and St. Louis (314-454-0058). (AACTG A5090)

HIV in Cerebrospinal Fluid and Potent Antiretroviral Therapy

This observational study will measure HIV levels in the blood and compare them to levels of HIV in CSF before and after the administration of anti-HIV therapy. Eligible participants must be starting a new, potent antiretroviral regimen; participation in another AACTG trial is no longer required. Before beginning the new anti-HIV regimen, participants will have blood tests and a lumbar puncture to see if there is any HIV in the CSF. Study visits will take place at six months, one year, and then once per year thereafter. During study visits participants will have a neurological exam, neuropsychological tests, blood tests, and a lumbar puncture. At the six-month visit participants will spend all day at the clinic for multiple blood tests to be taken throughout the day. Reimbursement for lumbar punctures will be available at most sites. Study locations include Baltimore (410-955-4370); Cleveland (216-778-5489); New York City (212-420-4432 or 212-263-6565); Rochester, NY (716-275-2740); San Francisco (415-514-0550 ext. 356); and Seattle (206-731-8877). (AACTG 736)

Mike Donnelly is the TrialScope coordinator of HIV InSite.

CORRECTION NOTICE

The Open Clinical Trials column in the Spring 2002 issue features a study under the heading "Decreased Mental Function: Segeline Patch." The correct name for this therapy is selegiline, not segeline.

HIV ADVOCACY GET INVOLVED

AIDS Treatment Activists Coalition (ATAC)

ATAC is a dynamic new coalition of people working together to improve HIV research and treatment access in the U.S.

ATAC encourages greater, more effective involvement of all people with HIV in decisions—made by the pharmaceutical industry, government, and others—that affect their lives. To bolster the ranks of treatment activists, the coalition is committed to identifying, mentoring, and empowering new activists in all communities affected by the epidemic.

ATAC Contact Information

Web site: www.atac-usa.org
Email: info@atac-usa.org

JOIN THE EMAIL LISTSERV—

send a message including your real name and a description of your AIDS treatment activism to:
info@atac-usa.org

Lifestyle Habits That Contribute to Optimal Health

- Eat a low-fat diet based in fruits, vegetables, and whole grains
- Exercise daily for at least 30 minutes
- Sleep at least eight hours every night
- Avoid smoking and second-hand smoke
- Reduce alcohol intake

RECYCLE YOUR MEDICATIONS!

THE FOLLOWING U.S. ORGANIZATIONS COLLECT ANTI-HIV MEDICATIONS FOR DONATION ABROAD. EACH ORGANIZATION FOLLOWS ITS OWN SET OF RULES; THE MAJORITY REQUEST THAT ALL DRUGS BE DELIVERED IN THEIR ORIGINAL PRESCRIPTION BOTTLES (ALL PATIENT AND DOCTOR NAMES WILL BE REMOVED BEFORE DISTRIBUTION).

AID for AIDS — New York, NY

212-337-8043
aid4aids@aol.com

AIDS Empowerment Treatment International (AIDSETI)

202-473-6637
www.aidseti.org

AIDS Medical Relief for Cuba — New York, NY

212-594-7741
babaluaye@aol.com

AIDS Medicine Recycling Project — San Francisco, CA

415-285-0606
510-411-1256
hobi@humanist.org

African AIDS Network — San Francisco, CA

415-440-3722
lwildes@aidseti.org

Being ALIVE — West Hollywood, CA

310-289-2551
progvoldir@aol.com

Human Rights Association of Agua Buena — Central America

510-841-1644
reynolds@rorl.ucsf.edu

International AIDS Empowerment — El Paso, TX

888-767-8474
skiproenthal@usa.com

Whitman Walker Clinic — Washington, DC

202-745-6149
mrelf@wwc.org

United Trauma Relief (UTR) — Cambridge, MA

617-225-8365
630-369-2474
utr@mit.edu