Open Clinical Trials

Below is a selected list of currently enrolling clinical trials gathered from various sources.

The federal government's **AIDSinfo** website includes a clinical trials section that features an introduction to HIV/AIDS research and study listings from the National Institutes of Health's **ClinicalTrials.gov** database. AIDSinfo also offers personalized advice about clinical trial participation via email (ContactUs@AIDSinfo.nih.gov), an interactive website (***www.aidsinfo.nih.gov/live_help***), and a toll-free telephone service (800-448-0440, international 301-315-2816).

Most U.S. government HIV/AIDS treatment trials are conducted by the **AIDS Clinical Trials Group** (ACTG). HIV prevention trials fall under the auspices of the **HIV Prevention Trials Network** (HPTN), the **HIV Vaccine Trials Network** (HVTN), and the **Microbicide Trials Network** (MTN). The other two trials networks funded by the National Institutes of Health are **International Maternal Pediatric Adolescent AIDS Clinical Trials** (IMPAACT) and the **International Network for Strategic Initiatives in Global HIV Trials** (INSIGHT). The **National Center for Complementary and Alternative Medicine** (NCCAM) conducts trials of complementary therapies for all conditions, including HIV/AIDS.

TrialSearch, operated by the **AIDS Community Research Initiative of America** (ACRIA), is a searchable online database of clinical trials related to HIV/AIDS. **CenterWatch** is a commercial website that includes trial listings for all diseases, including HIV/AIDS and related conditions. Trials of new drugs sponsored by pharmaceutical companies are often listed on company websites as well as ClinicalTrials.gov.

Call the telephone numbers listed for each study or see the indicated websites for further information about specific trials. Protocol numbers, if available, are provided in parentheses at the end of each trial description.

ACRIA TrialSearch: *www.acria.org/trials/current-drug-trials*
ACTG: *www.aactg.org*
AIDSInfo: *www.aidsinfo.nih.gov*
CenterWatch: *www.centerwatch.com*
ClinicalTrials.gov: *www.clinicaltrials.gov*
HIV Prevention Trials Network: *www.hptn.org*
HIV Vaccine Trials Network: *www.hvtn.org*
IMPAACT: *www.impaactgroup.org*
INSIGHT: *www.insight-trials.org*
Microbicide Trials Network: *www.mtnstopshiv.org*
NCCAM: *www.nccam.nih.gov/research/clinicaltrials*

Maraviroc and Endothelial Function

The University of California at San Francisco (UCSF), in conjunction with the National Heart, Lung, and Blood Institute (NHLBI), is conducting a Phase III trial to assess whether the CCR5 antagonist maraviroc (Selzentry) has beneficial effects on inflammation and endothelial (blood vessel lining) function in people with HIV (for background, see "Inflammation, Immune Activation, and HIV," page 12). Participants with persistently suppressed HIV viral load will be randomly assigned to add either 150 mg (with ritonavir) or 300 mg twice-daily maraviroc or placebo to their existing antiretroviral regimen for 24 weeks. Researchers will measure ability of the brachial (upper arm) artery to dilate, an indicator of endothelial function and subclinical atherosclerosis.

Eligible participants must be at least 18 years of age and have been on stable antiretroviral therapy with good adherence and consistently undetectable viral load for at least 12 months, with no plans to modify their regimen during the study. Exclusion criteria include current or prior use of any CCR5 inhibitors or integrase inhibitors, recent use of immune-modulating drugs, and active hepatitis B or C; women may not be pregnant and must agree to use contraception. The study will enroll 50 participants at UCSF (415-206-8257 or phsue@medsfgh.ucsf.edu). ***www.clinicaltrials.gov/ct2/show/NCT00844519*** (HIVCADRFA).

Chloroquine for Immune Activation

The National Institute of Allergy and Infectious Diseases (NIAID) is conducting a Phase II study (ACTG A5258) to test whether chloroquine—best known as a malaria treatment—can reduce the level of immune activation in people with HIV, as determined by CD38 molecules on CD8 T-cells; researchers will also look at levels of bacterial DNA and lipopolysaccharide (LPS), which trigger immune activation. In this crossover trial, participants will be randomly assigned to receive 250 mg once-daily chloroquine or placebo for 12 months, then will switch to the other assignment for an additional 12 months.

Eligible participants must be 18–65 years of age, have

a viral load of at least 10,000 copies/mL, a current CD4 cell count of 400 cells/mm^3 or higher, a nadir (lowest-ever) count not lower than 200 cells/mm^3, and no history of AIDS-defining illness. They must have been off ART for at least six months, with no plans to start during the study. Exclusion criteria include certain medical conditions (including hearing loss) and use of certain drugs; women may not be pregnant or breastfeeding and must agree to use contraception.

The study will enroll 30 participants at more than ten sites, including Aurora (303-724-0712), Baltimore (410-614-2766), Birmingham (205-975-7925), Chicago (312-695-4994), Cincinnati (513-584-8373), Cleveland (216-778-5489), Los Angeles (310-557-3798), Nashville (615-467-0154 ext. 109), New York (212-746-7198), Philadelphia (215-349-8092), San Diego (619-543-8080), and Washington DC (202-687-7387). ***www.clinicaltrials.gov/ct2/show/NCT00819390*** (ACTG A5258).

Omega-3 Fatty Acids to Prevent Atherosclerosis

Tufts University, in conjunction with NHLBI, is sponsoring a Phase IV study of the effect of omega-3 fatty acids on vascular (blood vessel) function and carotid intima-media thickness, an indicator of atherosclerosis. In this randomized trial, HIV positive people with high triglyceride levels will receive either two twice-daily capsules of an FDA-approved omega-3 product (Lovaza) or placebo for 24 months. Participants will undergo regular blood lipid monitoring and vascular assessments, including carotid (neck artery) intima-media thickness and brachial artery elasticity.

Participants must be 18–70 years of age, be on a stable ART regimen for the prior two months with no plans to change, and have a fasting triglyceride level of between 150 and 2,500 mg/dL. They may already be taking lipid-lowering drugs if on a stable regimen for at least eight weeks with no plans to change. Women may not be pregnant or breastfeeding and must agree to use contraception. Exclusion criteria include certain medical conditions including inflammatory diseases and regular use of fish oil before the study (unless they stop for eight weeks and triglycerides remain elevated). This study will enroll 150 participants at Tufts University School of Medicine in Boston (617-636-3636 or jul.gerrior@tufts.edu). ***www.clinicaltrials.gov/ct2/show/NCT01041521*** (LVZ112667, 1R01HL096585-01A1).

Combination Therapy for HIV Neuropathy Pain

NIAID is conducting ACTG A5252, a Phase II trial to assess whether methadone (an opioid) and duloxetine (a serotonin-norepinephrine reuptake inhibitor) reduce pain due to neuropathy in people with HIV. In this cross-over trial, all participants will receive duloxetine plus methadone placebo, duloxetine placebo plus methadone, both drugs together, and both placebos together, each for four weeks, but the order in which these regimens are taken will be randomly assigned. Participants will receive exams throughout the study and keep a pain diary.

Eligible participants must be at least 18 years of age and have an average pain intensity of 4 or more on an 11-point scale. Participants on ART must have been on a stable regimen for at least 30 days with no plans to change, and those not on ART should not plan to start during the study. Exclusion criteria include recent use of drugs that contribute to neuropathy, depression requiring medication, use of certain other medications, history of substance abuse or dependence, and various medical conditions; women may not be pregnant or breastfeeding.

The study will enroll 120 participants at sites in Atlanta (404-616-6313), Baltimore (410-614-2766), Boston (617-724-0072), Chicago (312-695-4994), Cleveland (216-778-5489), Houston (713-500-6751), Los Angeles (310-222-3848), and St. Louis (314-747-1098). ***www.clinicaltrials.gov/ct2/show/NCT00863057*** (ACTG A5252).

Telaprevir for HIV/HCV Coinfection

The hepatitis C virus (HCV) protease inhibitor telaprevir is the furthest along in development of the new oral drugs that directly target the HCV lifecycle. It has been extensively tested in people with hepatitis C alone and is now being studied in people with HIV/HCV coinfection. In this Phase IIa trial, sponsored by Vertex Pharmaceuticals, participants will be randomly assigned to receive 750 or 1,125 mg telaprevir or a matching placebo every eight hours in combination with once-weekly pegylated interferon alpha-2a (Pegasys) and 800 mg twice-daily ribavirin; telaprevir or placebo will be taken for 12 weeks, with pegylated interferon/ribavirin continued for 48 weeks.

Eligible participants must be 18–65 years of age and must be HIV positive (for more than six months) with HCV genotype 1 and a liver biopsy within the past year showing evidence of liver disease progression (inflammation and/or fibrosis). The first stage of the study will only enroll individuals who have not taken ART within the past year, but HIV treatment is permitted during the second stage. Exclusion criteria include prior use of interferon, ribavirin, or other investigational hepatitis C drugs.

The study will enroll 60 participants at about ten sites, including Baltimore, Beverly Hills, Boston, Chicago, Dallas, La Jolla, Miami, New York, Orlando, and San Francisco. For all sites, contact 877-634-VRTX or medicalinfo@vrtx.com. ***www.clinicaltrials.gov/ct2/show/NCT00983853*** (VX08-950-110).

Emergency Contraception and HIV Drugs

The University of Colorado at Denver is conducting a Phase I trial to assess whether the emergency hormonal contraceptive Plan B (levonorgestrel)—the "morning after" pill—can be safely used with the NNRTI efavirenz (Sustiva). Researchers will measure pharmacokinetic parameters of levonorgestrel prior to and while using efavirenz; adverse events and liver function will be evaluated after three weeks.

This small non-randomized, open-label study will enroll healthy HIV negative women 18–45 years of age. They must be pre-menopausal, not using current hormonal contraception, and not pregnant or breastfeeding. Other exclusion criteria include obesity and hepatitis B or C. Study sites are the University of Colorado Health Sciences Center in Denver (720-848-0819) and the Miriam Hospital in Providence, RI (401-793-4632). ***www.clinicaltrials.gov/ct2/show/NCT00482963*** (06-1178).

HIV Testing and HIV Health Resources

Knowing your HIV status is the first step toward staying healthy with HIV or remaining negative. As a *BETA* reader, chances are that you already know your HIV status—but do your friends and family members know theirs? Not everyone knows that they may be at risk for HIV, let alone that they may already have the virus. And not everyone knows where and how to get tested, and what to do if they find out they have HIV.

Please take advantage of these resources—all available in English and Spanish—to help keep yourself and those you care about safe and healthy.

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The following hotlines offer information and anonymous counseling about HIV testing, transmission, prevention, and health.

AIDS in Prison Hotline
1-718-378-7022 (U.S.; all collect calls accepted)
Hours: Tuesday, Wednesday, Thursday, 3 pm to 8 pm ET
809 Westchester Ave.
Bronx, NY 10455
www.osborneny.org/aids_in_prison_project.htm

California HIV/AIDS Hotline
1-800-367-AIDS (Toll-free within California)
1-415-863-AIDS (In San Francisco and outside California)
1-888-225-AIDS (TTY for the hearing impaired)
Hours: Monday, Wednesday, Thursday, Friday, 9 am to 5 pm PT; Tuesday 9 am to 9 pm PT

GMHC AIDS Hotline
1-800-AIDS-NYC (1-800-243-7692)
1-212-645-7470 (TTY)
1-212-807-6655 (International)
Hours: Monday through Friday, 10 am to 9 pm ET; Saturday, 12 pm to 3 pm ET
www.gmhc.org/hotline.html

National AIDS Hotline
1-800-CDC-INFO (1-800-232-4636)
1-888-232-6348 (TTY)
Hours: 24 hours a day, 7 days a week

Women Alive
1-800-554-4876 (U.S.)
1-323-965-1564 (International)
Hours: Monday through Friday, 11 am to 6 pm PT
1566 Burnside Ave.
Los Angeles, CA 90019
www.women-alive.org/index.htm

The National Prevention Information Network, part of the U.S. Centers for Disease Control and Prevention (CDC), can help you or someone close to you find an HIV testing site, and can help answer questions about HIV testing and HIV prevention.

CDC National Prevention Information Network
1-800-458-5231 (U.S.)
1-404-679-3860 (International)
Hours: Monday through Friday, 9 am to 6 pm ET
P.O. Box 6003
Rockville, MD 20849
www.hivtest.org/contact.cfm