

OPEN Clinical TRIALS

FOR HIV/AIDS TREATMENTS



Below is a partial listing of currently enrolling U.S. clinical trials gathered from various sources. **TrialScope** is a database of organizations that conduct HIV/AIDS-related research.

It provides contact information for each research site, links to organizational web sites, the types of research conducted by each site, and any affiliations with major multicenter research groups. The federal government's **AIDSinfo** site (which replaces the former AIDS Clinical Trials Information Service and the HIV/AIDS Treatment Information Service) includes a section on clinical trials. This site features an introduction to HIV/AIDS research and study listings from the National Institutes of Health's **ClinicalTrials.gov** database of trial listings for all diseases. AIDSinfo also has a toll-free phone service at 800-874-2572. Specialists are on hand Monday through Friday from 12:00 pm to 4:00 pm ET (9:00 am to 1:00 pm PT) to help locate trials and answer questions. Like ClinicalTrials.gov, the **CenterWatch** web site also includes trial listings for all diseases including HIV/AIDS and related conditions. **Community Programs for Clinical Research on AIDS (CPCRA)** is a nationwide network that conducts community-based clinical trials. The **AIDS Community Research Initiative of America (ACRIA)** provides a listing of trials in New York, New Jersey, Connecticut, and Pennsylvania.

Call the telephone numbers listed below or see the indicated web sites for more information about specific trials and a listing of study sites. Protocol (study) numbers are provided in parentheses at the end of each trial description.

ACRIA: www.criany.org/clinical/index.html

AIDSinfo: www.aidsinfo.nih.gov/clinical_trials

CenterWatch: www.centerwatch.com

ClinicalTrials.gov: www.clinicaltrials.gov

CPCRA: www.cpcra.org

TrialScope: www.hivinsite.org/tscope

ANTIRETROVIRAL THERAPY

TMC114

This study will look at the safety, efficacy, and tolerability of TMC114, a new protease inhibitor (PI), given with low-dose ritonavir (Norvir). Laboratory research suggests that TMC114 may be effective against HIV that has developed resistance to other PIs. This Phase II trial is for treatment-experienced subjects who have taken the first three classes of anti-HIV drugs—nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), and PIs. Four different doses of TMC114 will be compared. The study will include 300 participants in the U.S. and Puerto Rico and will last 48 weeks.

Eligible participants must be at least 18 years of age. They must have been on a stable (unchanged) antiretroviral regimen that does not include an NNRTI for at least eight weeks prior to the start of the study. In addition, they must previously have taken at least one NNRTI and two PIs. They must have a viral load of at least 1,000 copies/mL, and must have evidence of at least one PI-resistance mutation. Participants may not have any active AIDS-defining illness or hepatitis A, B, or C, and must not be using any other investigational agents.

The study is being conducted at more than 50 sites, including **Atlanta** (404-616-6313), **Baltimore** (410-614-1338), **Birmingham** (205-975-7925), **Boston** (617-778-5454 ext. 223), **Chapel Hill** (919-843-8761), **Chicago** (773-296-2400 Ext. 122), **Cincinnati** (513-584-8373), **Dallas** (214-828-4702), **Denver** (303-372-5537), **Houston** (713-500-5483), **Los Angeles** (323-913-1033), **Miami** (305-695-1300), **New York** (212-305-2665), **Philadelphia** (215-615-0122), **Phoenix** (602-307-5330), **San Diego** (619-543-8080), **San Francisco** (415-292-5477 ext. 481 or 415-476-9296 ext. 336), **San Juan** (787-722-1248), **Seattle** (206-731-8877), **Tampa** (813-844-4639), and **Washington, DC** (202-745-6150); www.clinicaltrials.gov/ct/show/NCT00071097. (TMC114-C202)

Comparing First-Line Regimens

This open-label, randomized Phase III study will compare three different regimens in people starting anti-HIV therapy for the first time. Participants will receive either an NNRTI-based regimen (efavirenz [Sustiva] plus 3TC [lamivudine, Epivir] plus either d4T [stavudine, Zerit], AZT [zidovudine, Retrovir], or tenofovir DF [Viread]), a boosted PI regimen (lopinavir/ritonavir [Kaletra] plus 3TC plus one of the same three NRTIs), or an NRTI-sparing regimen (lopinavir/ritonavir plus efavirenz). Study visits will take place every four weeks for 24 weeks, then every eight weeks for the remainder of the 96-week study. Body measurements and DEXA scans will be done at some of the visits to assess lipodystrophy. The study aims to enroll 660 participants.

Eligible participants must be at least 13 years of age. They must have a viral load of at least 2,000 copies/mL within 60 days of study entry. Subjects are ineligible if they have previously take any anti-HIV medications for more than seven days, or if they have ever taken 3TC or an NNRTI. Current or recent use of several other medications is also excluded. Women may not be pregnant or breast-feeding.

There are more than 60 study sites, including **Atlanta** (404-616-6313), **Baltimore** (410-706-2785), **Birmingham** (205-975-7925), **Boston** (617-632-0785), **Chicago** (312-942-4810), **Cleveland** (216-778-5489), **Dallas** (214-590-0414), **Denver** (303-372-5535), **Honolulu** (808-737-2751), **Indianapolis** (317-274-8456), **Los Angeles** (310-206-8029), **Miami** (305-243-3838), **Minneapolis** (612-625-1462), **Nashville** (615-467-0154 ext. 108), **New York** (212-263-6565), **Omaha** (402-559-8163), **Pittsburgh** (412-647-0771), **Providence** (401-793-4396), **Rochester** (585-275-2740), **San Diego** (619-543-8080), **San Francisco** (415-514-0550 ext. 354), **Seattle** (206-731-8877), **Stanford** (650-723-2804), **St. Louis** (314-454-0058), and **Washington, DC** (202-687-7387); www.clinicaltrials.gov/ct/show/NCT00050895; (ACTG A5142)

Once-Daily vs Twice-Daily HAART

This open-label Phase II study will compare once-daily versus twice-daily administration of antiretroviral drugs, and will also look at self-administered versus directly observed therapy. The trial is for people who are taking anti-HIV therapy for the first time. Participants will be randomly assigned to one of three study arms. All will receive the same daily dosages of lopinavir/ritonavir, FTC (emtricitabine, Emtriva), and extended-release d4T. Participants in Arm A will self-administer lopinavir/ritonavir twice daily, and FTC and d4T once daily for 48 weeks. Arm B participants will self-administer all three drugs once daily for 48 weeks. Those in Arm C will take all three drugs once daily in the presence of a clinician for 24 weeks, then by self-administration for 24 more weeks. The study will measure safety, efficacy, tolerability, and quality of life.

Participants must be at least 13 years of age and have a viral load of at least 2,000 copies/mL within 90 days of study entry. They must not have taken any anti-HIV drugs for more than seven days. Participants are ineligible if they have recently had certain illnesses or taken certain medications, including those that may cause pancreatitis (inflammation of the pancreas) or peripheral neuropathy. Women may not be pregnant or breast-feeding, and female and male participants must use effective contraception.

There are more than 20 sites, including **Baltimore** (410-614-4487), **Boston** (617-632-0785), **Cleveland** (216-778-5489), **Denver** (303-372-5535), **Indianapolis** (317-274-8456), **Miami** (305-243-3838), **New York** (212-263-6565), **Philadelphia** (215-349-8092), **Providence** (401-793-4396), **Rochester** (585-275-2740), **Sacramento** (916-734-8637), **San Juan** (787-767-9192), and **Seattle** (206-731-8877); www.clinicaltrials.gov/ct/show/NCT00036452. (ACTG A5073)

Salvage Therapy: Dual vs Triple PIs

This study will compare a regimen containing three PIs with two different regimens containing a PI boosted with ritonavir. The trial will look at the safety, efficacy, and tolerability of the three regimens, as well as concentrations of PIs in the blood. Participants will receive either lopinavir/ritonavir (Arm A), fosamprenavir (Lexiva) plus ritonavir (Arm B), or lopinavir/ritonavir plus fosamprenavir (Arm C). Subjects in all arms will also take tenofovir plus 1–2 other NRTIs, which will not be provided by the study. Blood will be drawn periodically to assess drug pharmacokinetics. The study aims to enroll 216 subjects.

Eligible participants must be at least 18 years of age. They must previously have used at least one PI and have at least one year of total antiretroviral use. They must have been on a stable regimen for at least 12 weeks and have had a viral load of more than 5,000 copies/mL within 60 days of prestudy screening. Participants are not eligible if they have previously used both amprenavir (Agenerase) and lopinavir for more than seven days each. They must not have recently used other investigational agents, cancer chemotherapy, immune-modulating drugs, agents that may damage the kidneys, or certain other medications. Women may not be pregnant or breast-feeding, and both female and male participants must use effective contraception.

There are more than 30 study sites, including **Atlanta** (404-616-6313), **Boston** (617-726-3819), **Chapel Hill** (919-843-8761), **Chicago** (312-695-5012), **Cleveland** (216-844-8051), **Dallas** (214-590-0414), **Denver** (303-372-5535), **Galveston** (409-747-0241), **Indianapolis** (317-274-8456), **Los Angeles** (323-343-8283), **Miami** (305-243-3838), **Nashville** (615-467-0154 ext. 108), **New York** (212-263-6565), **Philadelphia** (215-349-8092), **Pittsburgh** (412-647-0771), **San Francisco** (415-514-0550 ext. 362), **Seattle** (206-731-8877), and **Stanford** (650-723-2804); www.clinicaltrials.gov/ct/show/NCT00028366. (ACTG A5143)

OPTIMA: Mega-HAART and STI

This study will examine the benefits of “mega-HAART” regimens in people with advanced HIV disease for whom antiretroviral treatment with three current drug classes—NRTIs, NNRTIs, and PIs—has failed. It will also look at whether a three-month break from treatment can help reduce drug resistance and allow people to better tolerate therapy. Participants will be randomly assigned to either begin treatment immediately or undergo a three-month drug-free period. Once treatment begins, some subjects will receive mega-HAART regimens containing five or more anti-HIV drugs, while others will take standard HAART regimens of up to four drugs. Outcomes to be measured include viral load, immunological function, time to serious adverse side effects, time to AIDS-defining illness, and survival time. A projected 1,700 participants will be followed for an average of two years.

Participants must be at least 18 years of age. They must have been on continuous HAART for at least three months, and must be on therapy at the time of enrollment. In addition, they must have experienced failure of at least two different regimens that included NRTIs, NNRTIs, and PIs, or have laboratory test results that show resistance to drugs in each of these classes. While on their current regimen, candidates’ two most recent measurements must have shown a CD4 cell count of 300 cells/mm³ or less and a viral load above 2,500 or 5,000 copies/mL (depending on the test used). Subjects are ineligible if they are unable to tolerate multiple antiretroviral drugs or have recently had certain illnesses. Women may not be pregnant or breast-feeding.

The study will be conducted at 30 Veterans Affairs medical centers, including **Ann Arbor** (734-769-7100 ext. 5797), **Baltimore** (410-605-7199), **Boston** (617-232-9500 ext. 4669), **Cleveland** (216-791-3800 ext. 4788), **Dallas** (214-857-0410), **Los Angeles** (310-268-3015), **Miami** (305-324-4455 ext. 4800), **New York** (212-951-3348), **Philadelphia** (215-823-5847), **Phoenix** (602-277-5551 ext. 6796), **San Diego** (858-552-8585 ext. 2626), **San Juan** (787-641-2904), and **St. Petersburg** (727-398-6661 ext. 5905); www.clinicaltrials.gov/ct/show/NCT00050089. (CSP 512)

SMART: Drug Conservation vs Viral Suppression

The SMART study, conducted by the Terry Beinr Community Programs for Clinical Research on AIDS (CPCRA), is a large, simple trial comparing two HIV treatment strategies. The study will attempt to determine whether participants at low risk of disease progression can safely reduce their use of anti-HIV therapy, thus minimizing side effects, slowing the development of drug resistance, and conserving treatment options. Participants randomly assigned to the drug conservation arm will stop (or not start) anti-HIV therapy until their CD4 cell counts fall below 250 cells/mm³, at which point they will begin therapy and continue until their CD4 cell counts rise above 350 cells/mm³. Those assigned to the viral suppression arm

will continue (or start) treatment in an attempt to keep viral load as low as possible, regardless of CD4 cell count. Some 6,000 participants will be followed for an estimated 6–9 years, until 910 primary events (disease progression or death) occur. Selected participants will be followed with more intensive data collection for secondary outcomes related to cost, health-care utilization, metabolic complications of treatment, and quality of life.

Participants must be at least 13 years of age and have a CD4 cell count above 350 cells/mm³ within 45 days of study entry. Subjects may be using any antiretroviral or immune-modulating drugs at study entry. They must be in reasonably good health and available to continue the study for at least six months. Women may not be pregnant or breast-feeding, and both female and male participants must use effective contraception.

There are more than 60 study sites, including **Atlanta** (404-876-2317 ext. 324), **Boston** (617-778-5454), **Brooklyn** (718-270-4487), **Chicago** (773-244-5802), **Denver** (303-436-7195), **Detroit** (313-745-4431), **Houston** (713-500-6751), **Los Angeles** (323-860-7330), **Miami** (305-324-4455 ext. 4942), **Newark** (973-483-3444), **New Orleans** (504-584-1971), **New York** (212-939-2957), **Philadelphia** (215-707-8846 ext. 220), **Portland** (503-229-8428), **Richmond** (804-828-6471), **San Francisco** (415-476-9554, ext. 22), and **Washington, DC** (202-745-8301); www.clinicaltrials.gov/ct/show/NCT00027352, or www.smart-trial.org. (CPCRA 065)

When to Change Therapy

This randomized pilot study will compare the benefits of changing antiretroviral therapy when viral load is 200 copies/mL versus waiting to switch until viral load reaches 10,000 copies/mL. The trial will look at drug resistance, viral fitness, and immune reconstitution. Current U.S. HIV treatment guidelines recommend switching to a new regimen as soon as viral load starts to rise in order to minimize the development of drug resistance. But there is evidence that some people can still benefit from therapy even after viral rebound, and delaying a regimen switch may help preserve future treatment options. Participants with viral loads between 200 and 10,000 copies/mL will be randomly assigned to switch immediately (Arm A) or switch after a delay (Arm B). Arm A participants will receive genotypic resistance testing upon study entry and, based on these results, will switch to a new regimen within four weeks. Participants in Arm B will continue their current regimen and receive resistance testing when their viral load reaches 10,000 copies/mL or more; based on the results, they will then change their regimen within four weeks. Resistance testing and regimen switching will also take place if CD4 cell counts decline by 20% from baseline. All participants will be followed for at least 48 weeks after study entry. This trial does not provide drugs.

Eligible participants must be at least 13 years of age and have been on stable HAART for at least four months. They must have a CD4 cell count of at least 200 cells/mm³

within 45 days of study entry. Viral load must be detectable at enrollment, but must have been below 500 copies/mL prior to study screening while on the current regimen. Participants must not have certain illnesses and may not have recently used certain medications. Women may not be pregnant or breast-feeding, and subjects must be willing to use birth control.

There are 20 study sites, including **Boston** (617-726-3819), **Chicago** (312-942-5865), **Dallas** (214-590-0414), **Denver** (303-372-5535), **Durham** (919-668-0161), **Miami** (305-243-3838), **Nashville** (615-467-0154), **New York** (212-263-6565), **Pittsburgh** (412-647-0771), **Seattle** (206-731-8877), and **Stanford** (650-723-2804); www.clinicaltrials.gov/ct/show/NCT00036465. (ACTG A5115)

When to Start HAART in People with OIs

This study will attempt to determine when is the best time to start antiretroviral therapy in individuals presenting with opportunistic illnesses (OIs). Immediately starting HAART may be disadvantageous since anti-HIV drugs can cause immune reconstitution inflammatory syndrome and can interact with drugs used to treat OIs. This trial will compare the benefits and drawbacks of starting antiretroviral therapy immediately versus waiting until after OI treatment is underway or completed. Participants will be randomly assigned either to begin antiretroviral therapy within two months of starting OI treatment (Arm A), or to defer anti-HIV treatment until at least four weeks—but no more than 32 weeks—after beginning OI therapy. All subjects will receive lopinavir/ritonavir plus d4T, and may also receive a third and fourth anti-HIV drug at the discretion of study clinicians. The study will last 48 weeks and participants will have ten study visits, which will include blood tests, physical examinations, and questionnaires.

Eligible participants must be at least 13 years of age. They must have a confirmed or suspected acute OI, including *Pneumocystis carinii* pneumonia (PCP), bacterial pneumonia, cryptococcal meningitis, disseminated histoplasmosis, disseminated *Mycobacterium avium* complex (MAC), cytomegalovirus (CMV) retinitis or encephalitis, or toxoplasmic encephalitis. Participants may not have been on antiretroviral therapy within six months of study entry or for a total of six months at any time prior to joining the trial, and may not have been treated for their current OI for more than 14 days prior to study entry. Certain conditions and recent use of certain medications are excluded. Women may not be pregnant or breast-feeding, and subjects must be willing to use effective contraception.

The study will enroll 282 participants at more than 20 sites, including **Boston** (617-732-5635), **Chapel Hill** (919-843-8761), **Denver** (303-372-5535), **Galveston** (409-747-0241), **Indianapolis** (317-274-8456), **Miami** (305-243-3838), **New York** (212-305-2665), **Rochester** (585-275-2740), **San Francisco** (415-514-0550 ext. 354), **Stanford** (650-723-2804), and **St. Louis** (314-454-0058); www.clinicaltrials.gov/ct/show/NCT00055120. (ACTG A5164)

SIDE EFFECTS AND OTHER CONDITIONS

Alcohol and HCV Disease Progression

This study, sponsored by the National Institutes of Health (NIH) and conducted by the University of California at San Francisco (UCSF), will examine the effects of alcohol on the progression of chronic hepatitis C (HCV). It is well known that heavy alcohol consumption (more than 60–90 grams per day) is associated with more rapid liver disease progression. This prospective study will look at the effect of smaller amounts of alcohol.

Eligible participants must have HCV, and may or may not be coinfecting with HIV. Potential participants will be screened in person by study clinicians to determine eligibility. Subjects will receive a liver biopsy if they have not had one recently. Participants will be interviewed by telephone every six months about their alcohol use, and will receive an in-person interview, blood test, and physical examination annually for four years. Subjects will be compensated \$25–\$100 for each in-person visit and travel expenses will be reimbursed.

This study is being conducted in **San Francisco** (888-286-1821).

Leptin and HIV-Associated Lipodystrophy

This study, also conducted by UCSF, will look at whether leptin is useful in the treatment of insulin resistance, elevated blood fat levels, body fat changes, and other metabolic complications in people with HIV. Leptin is a hormone produced by fat cells that helps regulate appetite and promotes normal insulin activity. (See “Insulin Resistance and Diabetes” on page 41.)

Subjects will spend five days at San Francisco General Hospital (SFGH), where they will undergo tests of metabolism and body fat distribution. They will then receive twice-daily subcutaneous (under the skin) injections of recombinant (genetically engineered) human leptin for three months. They will then undergo another five-day testing period at SFGH. Then, the leptin dose will be increased for an additional three months, at which time subjects will undergo a final set of tests at the hospital. Brief assessments will be done between hospital stays. Subjects who complete the trial will receive \$1,000 in compensation.

Participants must be between 18 and 65 years of age, have a viral load below 10,000 copies/mL within 30 days of study entry, and be on a stable antiretroviral regimen with no plans to change therapy during the six-month study. In addition, subjects must have an elevated triglyceride level (or a history of elevated triglycerides before starting lipid-lowering medication) and either peripheral (face or limbs) fat loss or abdominal fat gain. Subjects must satisfy several laboratory criteria (including liver

enzyme levels) and may not be taking hormone therapy, including hormonal contraceptives. Women may not be pregnant or breast-feeding.

The study will be conducted in **San Francisco**. Contact study coordinator Hootan Khatami, MD, at 415-206-4185.

Metformin and Rosiglitazone for Fat and Insulin Abnormalities

This randomized, double-blind, placebo-controlled trial will evaluate the effect of metformin (Glucophage) and rosiglitazone (Avandia), taken alone or in combination, on elevated insulin levels and body fat accumulation in the abdomen and other areas. Metformin and rosiglitazone are currently approved by the Food and Drug Administration (FDA) for these indications in HIV negative people. Participants will be randomized to receive either metformin plus rosiglitazone, metformin plus rosiglitazone placebo, rosiglitazone plus metformin placebo, or placebos of both drugs. After 16 weeks, participants who remain in the study will be switched to an open-label phase and all will receive metformin plus rosiglitazone for an additional 16 weeks. Clinic visits will take place at weeks 2, 4, 8, 12, 16, 18, 20, 24, 28, and 32, and will include blood draws to assess insulin and glucose levels (this must be done after fasting overnight). In addition, visceral (internal) fat, subcutaneous fat, and thigh size will be measured.

Participants must be between 18 and 65 years of age and have a viral load below 10,000 copies/mL within 30 days of study entry. They must have specific blood insulin levels and meet physical restrictions based on height, weight, and amount and location of body fat. Subjects must be on a stable anti-HIV regimen for at least 60 days prior to study entry. Participants may not have previously taken drugs to control blood sugar. They may not be taking ritonavir with either simvastatin (Zocor) or lovastatin (Mevacor). Subjects are ineligible if they have certain conditions or have recently taken certain medications. Women may not be pregnant or breast-feeding, and female and male participants must be willing to use effective contraception.

There are more than 30 study sites, including **Baltimore** (410-614-4487), **Birmingham** (205-975-7925), **Boston** (617-726-3819), **Chapel Hill** (919-843-8761), **Chicago** (312-695-5012), **Cincinnati** (513-584-8373), **Denver** (303-372-5535), **Honolulu** (808-737-2751), **Indianapolis** (317-274-8456), **Los Angeles** (310-206-8029), **Nashville** (615-467-0154 ext. 109), **New York** (212-420-4432), **Omaha** (402-559-8163), **Pittsburgh** (412-647-0771), **San Francisco** (415-514-0550 ext. 362), **Seattle** (206-731-8877), **St. Louis** (314-454-0058), and **Washington, DC** (202-687-5378); www.clinicaltrials.gov/ct/show/NCT00015691. (ACTG A5082)

Blood Sugar Abnormalities in Pregnant Women

This study will look at the incidence of blood sugar abnormalities in HIV positive pregnant women taking

antiretroviral therapy. The trial will enroll 160 women, who will be followed every eight weeks from study entry through delivery, with a final visit 12 weeks after delivery. Glucose tolerance tests and other metabolic measurements will be performed. Newborn infants will also be evaluated at birth and at 12 weeks of age. This is an observational study of women already using anti-HIV therapy; drugs will not be provided.

Eligible women must be at least 13 years of age and be 20–24 weeks pregnant at study entry. They must have been on stable antiretroviral therapy including a PI for the eight weeks immediately prior to joining the study, and must plan to continue that regimen throughout the trial. Participants are not eligible if they currently have diabetes, although they may have a history of blood sugar problems during past pregnancies. Participants may not have a recent serious medical condition or have recently used certain medications, including steroids or drugs to control blood sugar or blood lipids (fats).

The study will be conducted at nearly 40 sites, including **Baltimore** (410-706-8933), **Birmingham** (205-558-2328), **Boston** (617-732-5635), **Chicago** (773-257-5717), **Cleveland** (216-844-8051), **Detroit** (313-745-7857), **Durham** (919-684-8216), **Honolulu** (808-737-2751), **Indianapolis** (317-274-8456), **Jacksonville** (904-244-5331), **Los Angeles** (323-226-2342), **Miami** (305-243-2154), **Minneapolis** (612-625-1462), **Nashville** (615-467-0154 ext. 105), **Newark** (973-972-3118), **New York** (212-263-6565), **Pittsburgh** (412-647-0771), **San Juan** (787-765-4186), **Seattle** (206-528-5020), **St. Louis** (314-454-0058), and **Washington, DC** (202-865-4578); www.clinicaltrials.gov/ct/show/NCT00017797. (ACTG A5084)

CHILDREN AND ADOLESCENTS

Weekly Drug Holidays for HIV Positive Adolescents

Few studies to date have been done in HIV positive adolescents, but as individuals infected at birth or as children reach their teen years, there is a growing need to better understand how they are affected by the virus and its treatment. This Phase II study will look at whether taking antiretroviral therapy on a four-days-on, three-days-off schedule can control HIV in 160 adolescents infected during childhood who have successfully maintained viral suppression with full-time therapy for at least six months. The study is motivated by concern about the cumulative effects of anti-HIV therapy and a desire to develop simpler regimens for teens.

Participants will be randomly assigned to receive either short-cycle therapy with three days off drugs each week, or standard continuous HAART. Subjects will be seen every other week for the first month, then monthly until the end of the 24-week study. HIV viral load and CD4

cell count will be assessed at every visit. Triglyceride and cholesterol levels will be measured at the beginning and the end of the study.

Eligible participants must be between 12 and 24 years of age and have been infected with HIV after age 9 (those infected perinatally are not eligible). They must have been on a stable antiretroviral regimen containing a PI but no NNRTIs or abacavir (Ziagen) for at least three months before study entry. In addition, they must have had three viral load measurements below 400 copies/mL within the past year, no measurements above that level within the past six months, and a viral load below 50 copies/mL within 30 days of study entry. They must also have a CD4 cell count of at least 350 cells/mm³. Participants are not eligible if they have certain illnesses or have recently taken certain medications. Females may not be pregnant, and subjects must be willing to use contraception.

The nine study sites are **Chicago** (312-572-4571), **Fort Lauderdale** (954-728-1125), **Los Angeles** (323-660-2450 ext. 3914), **Miami** (305-243-3442), **New York** (212-423-2867), **Philadelphia** (215-590-4954), **San Diego** (619-543-8080), **San Juan** (787-759-9595), and **Washington, DC** (202-884-3714); www.clinicaltrials.gov/ct/show/NCT00068809. (ATN 015)

Metabolic Abnormalities in Young Women

This study, also focused on adolescents, will look at metabolic complications in young women with HIV, including abnormal blood glucose and lipid levels, body fat changes, and bone density alterations. The study will compare metabolic parameters in HIV negative women, HIV positive women who have never used HAART, and HIV positive women taking regimens that include NNRTIs but no PIs, PIs but no NNRTIs, or neither PIs nor NNRTIs. In this cross-sectional observational study, participants will be seen only one time; the visit will include a questionnaire, a DEXA scan to assess body composition, and blood tests to assess glucose, lipid, and lactic acid levels.

Eligible participants must be females between 12 and 24 years of age. Both HIV negative and HIV positive participants are eligible; those with HIV may be taking any type of antiretroviral therapy or none at all. Subjects are not eligible if they have type 1 diabetes or type 2 diabetes that must be controlled with daily drugs. Participants may not be pregnant currently or within the past year.

Study sites include **Chicago** (312-572-4571), **Los Angeles** (323-660-2450 ext. 3914), **Miami** (305-243-3442), **New Orleans** (504-588-5348), **New York** (212-423-2867), **Philadelphia** (215-590-4954), **San Diego** (619-543-8080), **Tampa** (813-259-8799), and **Washington, DC** (202-884-3714); www.clinicaltrials.gov/ct/show/NCT00067587. (ATN 021)

Metabolic Manifestations in Children and Adolescents

Two currently enrolling studies will look at metabolic effects of antiretroviral therapy in HIV positive children

and adolescents. Research to date is conflicting as to whether anti-HIV drugs are associated with blood glucose abnormalities, elevated blood lipid levels, and/or body composition changes in children and adolescents with HIV.

I) The first study will look at how starting or changing anti-HIV therapy affects the growth and body composition of HIV-infected children, as well as the relationship between body composition, HIV viral load, and CD4 cell count. In addition, the study will examine cytokine (chemical messenger) levels and how these relate to body composition. This observational study will enroll children in four different age groups: 1 month to 18 months, 18 months to 3 years, 3 years to 8 years, and 8 years to 13 years. Participants will have five clinic visits, which will include anthropometric measurements; body composition assessment using bioelectrical impedance analysis; and blood tests for viral load, CD4 cell count, and markers of lipid and glucose metabolism.

Eligible children must be 1 month to 12 years of age and not yet have begun puberty. They must either be antiretroviral naive and starting anti-HIV therapy for the first time, be PI naive and starting PIs for the first time, or be changing to a new antiretroviral regimen that contains at least two drugs not previously used. Children are not eligible if they have certain disabilities or illnesses, including insulin-dependent diabetes, or have recently used certain medications.

The study is being conducted at 50 sites, including **Baltimore** (410-706-8933), **Birmingham** (205-558-2328), **Boston** (617-355-8198), **Chicago** (773-880-3669), **Denver** (303-861-6751), **Durham** (919-684-6335), **Houston** (832-824-2583), **Los Angeles** (323-226-2342), **Memphis** (901-495-2004), **Miami** (305-243-4447), **Newark** (973-972-3118), **New Haven** (203-688-6093 ext. 3498), **New York** (212-939-4045), **Oakland** (510-428-3885 ext. 2827), **Phoenix** (602-239-5261), **San Diego** (619-543-8080 ext. 236), **San Juan** (787-765-4186), and **Washington, DC** (202-865-1248); www.clinicaltrials.gov/ct/show/NCT00006064. (PACTG P1010)

II) The second study will measure insulin resistance in HIV positive children and adolescents taking PIs compared with those not taking this class of drugs. Children and adolescents starting PIs will be followed for two years to assess changes in insulin sensitivity. The study also will look at whether protein turnover (metabolism and utilization of proteins from food) and growth are affected by PI use.

Eligible participants must be between 7 and 18 years of age. Both HIV negative and HIV positive children and adolescents may join the study. Those with HIV may be either antiretroviral naive or experienced. Subjects may not have recently used certain medications, including steroids.

There are two study sites, **Houston** and **Salt Lake City**. Contact study coordinator Julie Rice at 801-585-9837; www.clinicaltrials.gov/ct/show/NCT00004739. (NCRR-M01RR02558)