Houston-area HIV/AIDS Clinical Trials Directory

The Center for AIDS Information & Advocacy

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Sponsored By

Community Advisory Board for the SMART Study (Houston-area Research Team)
Purpose of the Directory

This directory is designed to be a tool for the Houston-area HIV/AIDS community. The information contained within this directory provides details on clinical trials being conducted in the Houston area, though some trials may have additional research sites in other cities.

In the spirit of science, The Center for AIDS encourages all individuals to participate in clinical trials for which they may be eligible. However, safety is our first concern. **We strongly urge all individuals interested in participating in any clinical trial, including those listed in this directory, to first consult with their primary health care provider.** When seeing your health care provider, bring information that explains what you will need to do as a participant. Ask your health care provider if the clinical trial could negatively affect your health and if he or she thinks it is a good idea for you to participate. Please also review the "What is a Clinical Trial?" section of this directory for general information on clinical trials.

Resources

ACRIA’s TrialSearch

http://www.acria.org/clinical_trials

ClinicalTrials.gov

http://www.clinicaltrials.gov

Office for Research Protection

http://www.hhs.gov/ohrp/

University of Texas Medical Branch Galveston AIDS Clinical Trial Unit (ACTU)

http://www.actu.utmb.edu/ACTU/ACTUTrials.htm
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What is a “Clinical Trial?”

DEFINITION
A clinical trial is a research study that allows scientists and doctors to better understand the effects of an intervention (for example, a medication or surgical procedure). In the case of medications, clinical trials are necessary to gain approval by the US Food and Drug Administration (FDA).

A clinical trial may be used to examine any of the following:
• Whether an experimental medication works in people
• Which of two clinical approaches works best
• How a medication makes people feel
• Whether a surgery or procedure works

CLINICAL TRIAL PHASES
Clinical trials are divided into phases: Preclinical, 1, 2, 3, and 4. These trials are often used to study potential prescription medications, including HIV medications, before their actual approval. These phases are designed to examine different aspects of a treatment or therapy. The following explains what questions each phase of a trial is designed to answer:

Preclinical – How well does the treatment work (for example in fighting HIV) in the test tube? Does it work and is it safe in animals?

Phase 1 – Is the treatment safe for people?

Phase 2 – Does the treatment do what it is supposed to do in people?

Phase 3 – How does the treatment work after a long period of time in people or how does the treatment compare to the current treatment used for this condition (standard of care)?

Phase 4 – Now that the FDA has approved this treatment, is it still working well in people? Also, are there any unanswered questions about this treatment (such as, can pregnant women use this medication or are there long-term side effects)?

For more advanced studies (Phase 2 through 4), participants in clinical trials may be assigned to one of two groups. The first group is called the “treatment” group and the second is called the “control” group. The participants in the “treatment” group do receive the treatment, while the “control” group participants do not receive the treatment. In some studies, the “treatment” group receives the “study” treatment, while the control group receives the “standard of care” treatment.
If you participate in a clinical trial, you should not have to participate in all phases of the trial. Your role as a participant should be completely explained in the “informed consent form” (see below).

INCLUSION AND EXCLUSION CRITERIA
Clinical trials require participants to have certain characteristics AND to not have certain characteristics. These characteristics are different for each clinical trial.

“Inclusion Criteria” are the characteristics an individual MUST HAVE to be considered for participation in a clinical trial. For example, with a medication to treat HIV, the study participants must have HIV, or perhaps have more than a certain number of T cells.

“Exclusion Criteria” are characteristics an individual CANNOT HAVE to be considered for participation in a clinical trial. For example, with a new medication, pregnant women cannot participate if the risk of birth defects from the new drug is unknown.

In this directory, it is not possible to list all inclusion and exclusion criteria for each trial (some are quite lengthy). If you are interested in participating in a clinical trial, always check with the principal investigator (PI), the research coordinator, or the “contact” person about the specific inclusion and exclusion criteria for that trial.

INSTITUTIONAL REVIEW BOARD
An Institutional Review Board (IRB) is a group of individuals whose purpose is to protect the rights of people participating in clinical trials. IRBs were created by the National Research Act (1974) in response to the Tuskegee Syphilis Study (1932–1972), a study in which patients were treated unethically. The principal investigator (PI) of a clinical trial is responsible for meeting the IRB’s requirements for the use of human (and animal) subjects in their research before the trial begins, during the trial, and after the trial is over.

For more information on IRBs, visit the website of the US Government Office for Research Protection (Department of Health and Human Services) at http://www.hhs.gov/ohrp/.

INFORMED CONSENT
When signing up to participate in a clinical trial, a person is presented with an informed consent form. Those patients under 18 years of age must receive their parent or guardian’s signature on this form to participate in a clinical trial.

The informed consent form should be written in plain language that is easy to understand and include the following information:
• Complete information about the clinical trial including the purpose of the study, tests that you will undergo while participating, the medications you will take while participating, your rights as a participant, and the advantages and disadvantages of participating in this study.

• Contact information for the IRB responsible for the study AND the clinical trial’s PI.

ALSO...

• BEFORE signing the form, participants need to fully understand their role in the clinical trial. The participant may also receive a verbal explanation of the form and the clinical trial. Any questions a participant has should be answered by the PI or research coordinator.

• Participants should receive a copy of the form to take home with them, as well as a copy of any updates of the original consent form. These updates could include changes in how the study is being done or how the study information is being used.

POTENTIAL BENEFITS (PROS) FOR PARTICIPATING

Some potential benefits (PROS) to participating in a clinical trial include:

• Access to new medications not approved by the FDA
• A better relationship with healthcare providers (in other words, more time spent discussing your health with doctors)
• A good feeling that comes from helping others. The medical community will learn information from you that will be passed on to the community at-large. This could help improve the lives of others by offering new or better treatments for illnesses like HIV/AIDS, cancer, hepatitis, etc.

POTENTIAL LIABILITIES (CONS) FOR PARTICIPATING

Some potential liabilities (CONS) to participating in a clinical trial include:

• Safety and health concerns (for example, side effects of the new medication or the trial interfering with your current medical regimen)
• Uncomfortable procedures (for example, blood draws or staying overnight at a hospital/facility)
• Financial considerations (for example, time off from work or any out-of-pocket costs for expenses that the clinical trial does not cover).
YOU SHOULD ALSO KNOW

When participating in a clinical trial, keep in mind the following things:

- You should be given an informed consent form that explains the clinical trial. This form should be verbally explained to you in language that you can understand.
- You can drop out of the trial ANY TIME THAT YOU WISH.
- You should see your regular doctor as scheduled.
- You do not have to notify your employer, but procedures in some clinical trials may require time away from work (for example, lab work or doctor visits). When the trial is completed, you should be told the study results.
Antiretroviral Therapy/New Therapies

Panacos PA 103001-04 Study 203

Contact: Gerianne Casey  
Phone: 409-747-0214 or 1-877-324-2288  
Address: University of Texas Medical Branch Galveston (ACTU); 301 University Boulevard; Galveston, Texas 77555-0435

This study is examining an experimental HIV medication that is a part of a new class of HIV medications called “maturation inhibitors.” Maturation inhibitors work at a late stage in the HIV life cycle. The study drug is called PA 103001 and is a version of another experimental HIV maturation inhibitor called Bevirimat (PA-457). Researchers want to learn how safe the medication is in people and how well it controls HIV reproduction. People interested in participating in this study must meet several inclusion/exclusion criteria including: (1) must have a T-cell count greater than 200, (2) must not have any opportunistic infections (for example, PCP, toxoplasmosis, thrush), and (3) must be resistant to at least one class (non-nucleoside reverse transcriptase inhibitors [non-nukes], nucleoside reverse transcriptase inhibitors [nukes], protease inhibitors, or entry inhibitors) of HIV medications. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

A Phase 2 Study in Treatment-experienced, HIV-positive People Comparing Ritonavir (Norvir)-boosted GS-9137 (experimental HIV medication) with a Ritonavir (Norvir)-boosted Protease Inhibitor in combination with other HIV Medications

Contact: Kenneth Degazon  
Phone: 713-526-9821  
Address: Therapeutic Concepts PA; 4900 Fannin Street; Houston, Texas 77004  
Email: research@josephgathe.com

This study seeks to determine if an experimental HIV medication called an “integrase inhibitor” (GS-9137) plus ritonavir (Norvir) works better to control HIV than currently available protease inhibitors. Individuals interested in this study must meet inclusion and exclusion criteria including, but not limited to, the following: (1) HIV viral load greater than or equal to 1,000 copies, (2) must have taken HIV medication from at least 2 different classes (groups of HIV medications that fight the virus in different ways). There are 4 HIV classes including non-nucleoside reverse transcriptase inhibitors (non-nukes), protease inhibitors, entry inhibitors, and nucleoside reverse transcriptase inhibitors (nukes). Study participants should also (3) not be breastfeeding, and (4) not have an opportunistic infection (PCP, toxoplasmosis, etc.) within 30 days before starting the study. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
**Study of Aldesleukin with and without HIV Medications (STALWART)**

**Contact:** Hilda Cuervo  
**Phone:** 713-500-6751  
**Address:** University of Texas-Houston School of Medicine; Houston, Texas 77030  
**Email:** hilda.cuervo@uth.tmc.edu

This study will investigate a type of interleukin-2 called aldesleukin (an experimental medication). Interleukin-2 assists the body in making T cells. The study will determine if interleukin-2 lowers HIV viral load better when given by itself or when it is given in combination with other HIV medications. Interested people must meet certain inclusion and exclusion criteria including: (1) must have a T-cell count that is greater than or equal to 300, (2) must be able to begin taking an HIV treatment that includes 1 protease inhibitor and 2 non-nucleoside reverse transcriptase inhibitors (non-nukes), (3) must not have used interleukin-2 before, and (4) must not have used corticosteroids or received chemotherapy or experimental cytotoxic drugs within 45 days before starting this study. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

**HIV Study of Fosamprenavir (Lexiva) versus Lopinavir/Ritonavir (Kaletra), Both with Abacavir (Ziagen)/Lamivudine (Epivir) in Therapy-naive Patients**

**Contact:** Stephanie Alexander  
**Phone:** 713-799-1117 ext. 231  
**Address:** Infectious Diseases Associates; 6560 Fannin Street; Suite 1540; Houston, Texas 77030

This randomized (placed by chance), multicenter study will compare the safety and effectiveness of fosamprenavir (Lexiva) plus ritonavir (Norvir) versus lopinavir/ritonavir (Kaletra) over 48 weeks in HIV-1-positive patients who have never taken HIV medications before. The participants will also use the abacavir (Ziagen)/lamivudine (Epivir) fixed-dose combination tablet as a nucleoside reverse transcriptase inhibitor (nuke) backbone. Individuals interested in this trial must meet extensive inclusion and exclusion criteria including: (1) must not have received more than 14 days of prior treatment with HIV drugs and (2) must not be enrolled in other HIV treatment studies. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Behavior and HIV

Positive Choices

Contact:  Janel Dennison  
Phone:  713–520-8928  
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3400 Montrose, Suite 903; Houston, Texas 77006  
Email:  janel.m.dennison@uth.tmc.edu

This is a multipurpose clinical trial that will, in part, examine adherence (how well someone takes medication as directed, with respect to number of timing of doses) to HIV medications among HIV-positive African Americans who use recreational/street drugs. Interested individuals must meet extensive inclusion and exclusion criteria including, but not limited to, (1) being African American, (2) being a substance abuser, and (3) being HIV-positive. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria, as well as other areas to be explored by the study.
Children

Safety and Effectiveness of CD4-IgG2 in HIV-positive Children

Contact:  Chivon D. Jackson  
Phone:  832-824-1339  
Address:  Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030  
Email:  cdjackso@texaschildrenshospital.org

The purpose of this study is to determine if giving CD4-IgG2 to children who are HIV-positive is safe and helpful in fighting their HIV disease. CD4-IgG2 is an experimental drug that is designed to keep HIV from entering CD4 cells (T cells). Children interested in this study must meet inclusion/exclusion criteria including: (1) must be 2 to 12 years of age, (2) must be on a stable, unchanged HIV medication regimen for 3 months before starting the study, (3) must not have an HIV-related opportunistic infection, and (4) must not have received a vaccine within 30 days before starting the study. Parents or guardians of interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Pharmacokinetic Study of HIV Medications Taken During Pregnancy

Contact:  Chivon D. Jackson  
Phone:  832-824-1339  
Address:  Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030  
Email:  cdjackso@texaschildrenshospital.org

The purpose of this study is to determine what doses of HIV medications are safe for pregnant women. People interested in this study must meet inclusion/exclusion criteria including: (1) must be at least 20 weeks (5 months) pregnant, (2) must be enrolled in the PACTG P1025 clinical trial, (3) must not be pregnant with more than one baby, and (4) must not be on medications that interfere with the HIV medications being used in the study. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Sleep, HIV Disease Progression, and Function in HIV-infected Children and Adolescents

Contact: Chivon D. Jackson  
Phone: 832-824-1339  
Address: Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030  
Email: cdjackso@texaschildrenshospital.org

The purpose of this study is to explore how HIV affects sleep in HIV-positive children. Specifically, the study will examine changes in sleep-regulating cytokines (components of the immune system) and cytokines that fight HIV disease in children. People interested in this study must meet inclusion/exclusion criteria including: (1) must be 8 to 17 years old, (2) must be HIV-positive and (3) must not be pregnant. Interested individuals or legal guardians of minors should speak with the study contact person for complete inclusion and exclusion criteria.

HIV Drug Regimens with or without Protease Inhibitors and Drug Level Tests in Adolescents

Contact: Chivon D. Jackson  
Phone: 832-824-1339  
Address: Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030  
Email: cdjackso@texaschildrenshospital.org

This study will examine the effectiveness of using protease inhibitors in HIV treatment regimens being taken by children and adolescents. The study will also examine if monitoring the drug level of protease inhibitors in the body and adjusting the dose of protease inhibitors when they are being taken by children will make the medications more helpful in fighting HIV in children. Individuals interested in participating in this clinical trial will have to meet extensive exclusion and inclusion criteria including, but not limited to: (1) having a viral load of 10,000 copies or more, (2) weighing more than 75.2 lbs, and (3) must be sensitive to lopinavir/ritonavir (Kaletra), if currently taking a protease inhibitor. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Factors Affecting Adherence to HIV Drug Regimens in Children and Adolescents

Contact: Chivon D. Jackson  
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Address: Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030  
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This study will examine the problems that children and adolescents have when taking HIV medications. Specifically, this study will look at children’s ability to cope with the responsibility of taking HIV medications and their language skills, memory, academic skills, behavior, and attention span. Individuals will have to meet certain exclusion and inclusion criteria including, but not limited to, currently being enrolled in the following clinical trial: PACTG 219C – “Long-term Effects of HIV Exposure and Infection in Children.” Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Atazanavir (Reyataz) Used in Combination with Other HIV Medications in HIV-infected Infants, Children, and Adolescents

Contact: Chivon D. Jackson
Phone: 832-824-1339
Address: Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030
Email: cdjackso@texaschildrenshospital.org

The purpose of this study is to examine the safety and proper dose of atazanavir (Reyataz) with or without boosting by ritonavir (Norvir) in children. There are extensive inclusion and exclusion criteria for this study including: (1) must have a viral load of 5000 or more copies, (2) must be able to swallow the medication, (3) must not have hepatitis, and (4) must not have a history of heart problems. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Safety and Effectiveness of Emtricitabine (Emtriva) Taken Once Daily with Efavirenz (Sustiva) and Didanosine (Videx) in HIV-infected Children Who Have Taken Few or No Antiretroviral Medications

Contact: Chivon D. Jackson
Phone: 832-824-1339
Address: Texas Children's Hospital/Baylor College of Medicine; Houston, Texas 77030
Email: cdjackso@texaschildrenshospital.org

The purpose of this study is to examine the long-term treatment effects of emtricitabine (Emtriva), efavirenz (Sustiva), and didanosine (Videx) taken together, once a day in children. Interested individuals must meet extensive inclusion and exclusion criteria including, but not limited to: (1) must be 90 days to 21 years old, (2) must have never taken antiretroviral drugs or must have gotten no more than 56 days of antiretroviral drugs to prevent HIV infection at birth, or have gotten less than 7 total days of antiretroviral drugs as a treatment after birth, and (3) must not have had a serious medical event within 21 days before the screening visit. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
PACTG P1045: Prevalence of Morphologic Abnormalities in Children who are HIV-positive or Who Are HIV-negative

Contact: Chivon D. Jackson  
Phone: 832-824-1339  
Address: Texas Children's Hospital/Baylor College of Medicine;  
Houston, Texas 77030  
Email: cdjackso@texaschildrenshospital.org

The purpose of this study is to examine the bone density, fat levels, and blood sugar levels of young people with HIV. The study is attempting to understand how HIV medications may cause young people to develop certain types of metabolic and physical conditions, for example, changes in body fat distribution (lipodystrophy or lipoatrophy), bone development problems, dyslipidemia (high levels of fat in the blood), etc. Participants will be required to take a DXA scan (a test that scans the bones to determine how healthy they are) and answer questions about how their body has changed and about the foods they eat. Interested participants must meet extensive inclusion and exclusion criteria including: (1) must be 7 to 25 years old, (2) must have gotten HIV at birth, if HIV-positive, (3) can be HIV-positive or HIV-negative, (4) if participant is taking a protease inhibitor (PI) he or she must have been taking it for at least 1 year, and (5) must not be taking growth hormones or anabolic steroids within 6 months of participating in the study. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Safety of Saquinavir (Invirase/Fortovase) and High Doses of Lopinavir/Ritonavir (Kaletra) in HIV-positive Children

Contact: Chivon D. Jackson  
Phone: 832-824-1339  
Address: Texas Children's Hospital/Baylor College of Medicine;  
Houston, Texas 77030  
Email: cdjackso@texaschildrenshospital.org

The purpose of this study is to determine the effect of high doses of lopinavir/ritonavir (Kaletra) and saquinavir (Invirase/Fortovase) in children whose current HIV medications are no longer working. People interested in this study must meet inclusion/exclusion criteria including: (1) must have an HIV viral load greater than 5000 copies, (2) must have been on continuous therapy with a protease inhibitor (PI) for at least 6 months, (3) must not be on chemotherapy, and (4) must not have an opportunistic infection that is requiring treatment. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Co-conditions/Opportunistic Infections

ACTG A5178: Treatment Trial for HIV and Hepatitis C Virus (HCV) Co-infection with Liver Fibrosis (Scarring)

Contact: Cheryl Mogridge  
Phone: 409-747-0214 or 1-877-324-2288  
Address: University of Texas Medical Branch Galveston (ACTU); 301 University Boulevard; Galveston, Texas 77555-0435

This study will examine whether long-term treatment with pegylated-interferon (a medication used to treat HCV) slows down liver damage in people who have both HCV and HIV. People interested in participating in this study must meet the following inclusion/exclusion criteria: (1) must have a viral load of 50,000 copies or less, (2) must have a T-count greater than 200, (3) must not have hepatitis B, and (4) must have had a liver biopsy (test that removes a small piece of liver tissue) within the last two years that shows liver fibrosis. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

ACTG A5184: An Antiretroviral Treatment for HIV/HCV Co-infected Subjects Naïve to Treatment

Contact: Gerianne Casey  
Phone: 409-747-0214 or 1-877-324-2288  
Address: University of Texas Medical Branch Galveston (ACTU); 301 University Boulevard; Galveston, Texas 77555-0435

This study will examine the effect of treating HIV/HCV co-infected people with high T-cell counts for both infections at the same time. Participants will be given HIV antiretrovirals and pegylated-interferon plus ribavirin (2 medications considered to be standard treatment for HCV infection). Researchers will determine if the HIV medications make the HCV medications more or less useful for people who are co-infected with HCV. People interested in participating in this study must meet certain inclusion/exclusion criteria including the following: (1) must have a T-cell count of at least 300, (2) must have a viral load greater than or equal to 1,000 copies, and (3) must not be on any HIV medications. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Longitudinal Study of Ocular Complications of AIDS (LSOCA)

Contact: Steve Spencer  
Phone: 713-798-5969  
Address: Baylor College of Medicine; 1 Baylor Plaza, NC 206; Houston, Texas 77030

LSOCA is an observational study that aims to provide information on the incidence and course (or development) of ocular (eye) complications of AIDS. The study aims to: (1) examine how cytomegalovirus (CMV) retinitis and other ocular complications develop in HIV-positive people, (2) determine the effect of highly active antiretroviral therapy (HAART)-induced changes in immune status on the risk of CMV retinitis and other ocular complications of AIDS, (3) determine which types of patients are at high risk of CMV retinitis and other ocular complications of AIDS, and (4) evaluate the effects of treatments of CMV retinitis and other ocular complications on visual function, quality of life, and survival. Interested participants must (1) be diagnosed with AIDS according to the 1993 Centers for Disease Control definition and (2) be 18 years or older or aged 13 to 17 years old (with permission granted from a parent or legal guardian). Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

A Study of the Effectiveness and Tolerability of Weekly Rifapentine/Isoniazid for 3 Months versus Daily Isoniazid for 9 Months for the Treatment of Latent (Not Active) Tuberculosis (TB) Infection

Contact: Ruby Nickson  
Phone: 713-873-4105  
Address: Thomas Street Clinic; 2015 Thomas Street; Houston, Texas 77009  
Email: rnickson@bcm.tmc.edu

Contact: Terry Scott  
Phone: 713-873-4054  
Address: Thomas Street Clinic; 2015 Thomas Street; Houston, Texas 77009  
Email: tscott@bcm.tmc.edu

The primary objective of this Phase 3 clinical trial is to compare a regimen of rifapentine (an antibiotic for TB treatment) and isoniazid (an antibiotic for TB treatment) taken weekly for 3 months to a regimen of isoniazid taken daily for 9 months. Researchers want to see which treatment works better. Individuals interested in this study must have a skin reaction to tuberculin that indicates they require treatment of latent (not active) infection to prevent TB. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
CHARTER is an observational study that wants to determine the prevalence and characteristics of central nervous system (CNS) complications of HIV infection in the era of potent combination HIV therapy (also called HAART). This study involves extensive neurobehavioral and neuromedical testing, which will assess your reflexes, brain function, motor skills, and how well you solve problems. There are 3 stages to the study. All HIV-positive persons ages 18-65 are eligible for screening (Stage I). Minors age 16-17 are eligible with their consent and parental permission. A 30-45 minute screening interview can be done at UTMB or Thomas Street Clinic in Houston. Stage II and Stage III testing (requires 6-8 hours) is done at UTMB only. Compensation is available for time and inconvenience. Interested individuals should speak to the study contact person for complete inclusion and exclusion criteria.
Texas Repository for AIDS Neuropathogenesis Research

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Contact: Terry Scott  
Phone: 713-873-4054  
Address: Thomas Street Clinic; 2015 Thomas Street; Houston, Texas 77009  
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Contact: Phyllis Crawford  
Phone: 409-747-9522  
Address: University of Texas Medical Branch at Galveston; 301 University Boulevard; Galveston, TX 77555-0187  
Email: pecrawfo@utmb.edu

This clinical trial aims to examine the effect of HIV infection on the brain and nervous system. Participants will have tests that examine their nervous system and mental state, and the researchers will look at what medications patients have been using. Participants will also give samples of their blood and urine. These tests will be done every 6 to 12 months. In addition, participants may be asked to give a sample of their cerebral spinal fluid, which would be collected by lumbar puncture (spinal tap). This portion of the testing is optional (that is, can be refused). However, participants are required (that is, they have to) to have an autopsy and to donate their organs to research if they die while participating in this clinical trial. Compensation is available for time and inconvenience. To participate in this clinical trial, individuals must: (1) have a T-cell count less than 50 or (2) have a life-threatening condition, such as cancer, heart disease, lung disease, or liver disease. Interested individuals should speak to the study contact person for complete inclusion and exclusion criteria.
Fat Metabolism/Lipodystrophy

The Effects of Leptin Therapy on Fat Metabolism in HIV-positive Individuals

Contact: Edith Cuevas
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Address: Baylor College of Medicine; Dept. of Medicine; BCM 285/BCM 700B; 1 Baylor Plaza; Houston, Texas 77030
Email: cuevas@bcm.tmc.edu

People with lipodystrophy have problems with fat metabolism. Leptin is a substance in the body that controls the breakdown of fat. Levels of leptin may be low in some people infected with HIV. HIV-positive patients with low leptin levels are eligible to participate in this study looking at the effects of leptin treatments (given by injection) on fat metabolism. A 2-hour screening is needed to measure your natural level of leptin. If you qualify and decide to participate, 3 visits to the Clinical Research Center will be required: one visit before starting leptin therapy, one visit 2 months after starting leptin, and one visit 4 months after starting leptin. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Heart Positive Study

Contact: Sarah Clements, RN
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HIV infection and the HIV medications used to treat the virus can cause increases in an individual's risk for heart disease. A condition known as lipodystrophy, which results in changes in body fat, high levels of fat in the blood, and high levels of sugar (glucose) in the blood, is sometimes associated with this increased risk. This study aims to examine why this occurs. This study will test the effects of lifestyle changes and FDA-approved medications that are used to treat high levels of cholesterol and triglycerides (fats in the blood). To be eligible for this study, individuals must be (1) 18 to 65 years of age, (2) HIV-positive, and (3) have been receiving antiretroviral therapy for at least 6 months. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
ACTG A5206: Evaluating the Effects of Tenofovir (Viread) on Dyslipidemia in Individuals on a Stable HIV Medication Regimen

Contact: Gerianne Casey
Phone: 409-747-0214 or 1-877-324-2288
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This study is a 32-week study designed to determine if adding tenofovir (Viread) to a person’s HIV medication regimen will lower the lipid (fat in the blood) levels in the blood of people living with HIV who have dyslipidemia (abnormal lipid levels in the blood). To be eligible, individuals must meet exclusion and inclusion criteria including, but not limited to, the following: (1) must be 18 years old or older, (2) must have a triglyceride level that is greater than 200, but less than 1000, (3) must have a T-cell count greater than 400, (4) must be taking a stable HIV medication regimen for at least 90 days before starting the study, and (5) must have a non-high density lipoprotein (HDL) cholesterol level greater than 160, but less than 250. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

ACTG A5209: Treatment Trial for the Safety, Efficacy and Tolerability of Ezetimibe (cholesterol lowering drug) in Combination with Statin Medication (Cholesterol-lowering Medication)

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This is a 28-week study designed for people receiving statin therapy. To be eligible, individuals must meet exclusion and inclusion criteria including, but not limited to, the following: (1) must be receiving a stable HIV medication regimen, (2) must be receiving pravastatin (Pravachol), atorvastatin (Lipitor), or fluvastatin (Lescol) for at least 3 months (3) must be on a lipid-lowering diet (lipids are fats in the blood), (3) must be exercising for at least 30 days before starting study, (4) must not have diabetes, and (5) must not have coronary heart disease. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
ACTG A5229: A Phase II/III, Randomized, Double-blind, Placebo-controlled Trial of Uridine Supplementation in HIV Lipoatrophy (Fat Loss)

Contact: Gerianne Casey  
Phone: 409-747-0214 or 1-877-324-2288  
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This study will examine the effect of uridine (a substance that can be naturally found in the body) supplements (NucleomaxX) on limb fat in HIV-1 infected subjects receiving stable antiretroviral therapy containing d4T (Zerit) or ZDV (AZT, Retrovir). The study will also assess how safe and tolerable NucleomaxX is in patients. Potential participants must have clinical lipoatrophy (fat loss) in at least 2 of the following regions: face, arms, legs, or buttocks as assessed by both the physician and the participant. Individuals interested in participating must meet inclusion/exclusion criteria including: (1) having a viral load less than or equal to 5000 copies and (2) must not have diabetes. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
ROCHE ML 197BLQ Study – A Multicenter, Open-label Study Evaluating the Safety and Efficacy of a New Investigational Protease Inhibitor (PI) with Fuzeon (enfuvirtide or T-20) Plus Background Antiretroviral Regimen in HIV-1 Infected, Triple-class Treatment-experienced Patients

Contact: Georgia Melville, LVN  
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This study will examine an investigational HIV medication in combination with Fuzeon in people who have taken HIV medications from the other currently available classes of HIV therapy (nucleoside reverse transcriptase inhibitors [nukes], non-nucleoside reverse transcriptase inhibitors [non-nukes], and protease inhibitors). Individuals interested in this study must meet the following inclusion/exclusion criteria: (1) not be pregnant or breastfeeding, (2) be 18 years old or older, (3) must never have taken Fuzeon, (4) be willing to use birth control, and (5) have taken HIV medications from the other currently available classes of HIV therapy (nukes, non-nukes, and protease inhibitors). Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Vaccines to Prevent HIV Infection

Prevention of HIV Infection with Merck (MRK) Ad5 HIV-1 gag Vaccine (An Investigational HIV Vaccine)

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This study is examining the MRK vaccine to see what kind of role it may have in prevention of HIV infection. Study participants will be randomly assigned (placed by chance into a group) to receive 3 injections of the MRK vaccine or a placebo (a harmless solution). Inclusion and exclusion criteria for this study include (1) must be 18 to 45 years old, (2) **MUST BE HIV-NEGATIVE**, (3) must not have been in an HIV vaccine study before. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
The purpose of this study is to see whether one HIV medication (the protease inhibitor lopinavir/ritonavir) is strong enough to be used by itself (“monotherapy”) to suppress HIV. Using a single HIV medication is a very experimental approach and is not supported by past research. Current HIV treatment guidelines recommend combination therapy with agents from at least 2 classes of HIV medications. The guidelines do not recommend monotherapy. However, results from pilot studies in a small number of people indicate that such an approach may be possible with this protease inhibitor. It is important to understand all the potential risks involved before agreeing to participate in this study. If effective, this experimental approach could help shape future treatment guidelines, in addition to saving money on HIV treatment for some patients (depending on disease stage and other factors). For complete eligibility criteria and other information about this clinical trial, speak with the study contact listed above.
Naïve or New to Antiretroviral Treatment

ACTG A5202: An Antiretroviral Treatment for Naïve Patients

Contact: Gerianne Casey
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This study will examine the effects of 4 different HIV medication regimens in HIV-positive individuals who have not taken HIV medications before. Participants will be randomized (placed by chance) into one of 4 different groups. All of these groups will receive a drug regimen containing HIV medications and a placebo (a pill with no effect). The groups are as follows: Group 1: efavirenz (Sustiva), emtricitabine/tenofovir (Truvada), and a placebo version of abacavir/lamivudine (Epzicom); Group 2: efavirenz (Sustiva), abacavir/lamivudine (Epzicom), and a placebo version of emtricitabine/tenofovir (Truvada); Group 3: atazanavir (Reyataz), ritonavir (Norvir), emtricitabine/tenofovir (Truvada), and a placebo version of abacavir/lamivudine (Epzicom); and Group 4: atazanavir (Reyataz), ritonavir (Norvir), abacavir/lamivudine (Epzicom), and a placebo version of emtricitabine + tenofovir (Truvada). Interested individuals must meet extensive inclusion and exclusion criteria for this study including (1) never received antiretroviral medications or having taken HIV medications for 7 days or less, (2) must have a viral load greater than or equal to 1000 copies, and (3) must not have cardiac conduction disease. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

ACTG 5175: Study for Patients Naïve to Antiretroviral Treatment

Contact: Gerianne Casey
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Address: University of Texas Medical Branch Galveston (ACTU); 301 University Boulevard; Galveston, Texas 77555-0435

This study is designed to examine the effectiveness of a once-daily regimen versus a twice-daily regimen of HIV medications. Participants will be assigned to one of 3 groups that will receive a specific HIV regimen. The first group will receive lamivudine/zidovudine (Combivir) + efavirenz (Sustiva). The second group will receive emtricitabine (Emtriva) + zidovudine (Retrovir) + didanosine (Videx). The third group will receive emtricitabine (Emtriva) + tenofovir (Viread) + efavirenz (Sustiva). Individuals interested in this study must meet the following criteria: (1) must not be taking HIV medications (An exception may be made for people who have taken less than 7 days of HIV medications. Medications should have been taken at least 30 days before starting the study), (2) must have a T-cell count less than 300, and (3) other than HIV disease, must have no recently occurring illnesses. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
This study will examine 2 things. First, it will compare hard tablet Kaletra and soft gel capsules of Kaletra to determine which one is tolerated best by the body, safer for individuals to take, and best at fighting HIV in the body. Second, the study will compare once-a-day dosing of Kaletra plus nucleoside reverse transcriptase inhibitors (NRTIs) to twice-a-day Kaletra plus NRTIs in people who have never taken HIV medications. To participate in this study, a person must meet the following inclusion/exclusion criteria: (1) be 18 years of age or older, (2) must not have taken any HIV medications (An exception may be made for people who have taken less than 7 days of HIV medications. Medications should have been taken at least 30 days before starting the study.), and (3) be willing to use birth control. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Pregnant Women

Comparison of HIV Drug Combinations to Prevent Mother-to-Child Transmission of HIV

Contact: Chivon Jackson  
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The purpose of this study is to examine the effect of 2 different HIV treatment regimens on lowering the risk of transmitting HIV to unborn babies. This study will examine the following 2 HIV medicine combinations (1) abacavir/lamivudine/zidovudine (Trizivir) and (2) zidovudine/lamivudine (Combivir) + lopinavir/ritonavir (Kaletra). Inclusion and exclusion criteria must be met to participate in this study including, but not limited to, the following: (1) must be between 12 and 30 weeks pregnant, (2) must have a viral load less than 55,000 copies, and (3) must intend to stop taking HIV medications after giving birth. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Trial of 3 Neonatal HIV medication Regimens for Prevention of Intrapartum (during labor or delivery of the baby) HIV Transmission

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Researchers know that giving babies HIV medications immediately after birth can lower the babies’ risk of getting HIV from the mother. This study will examine the safety of 2 different HIV treatment regimens and a regimen containing only one HIV medication. All of these regimens are used to prevent mother-to-child transmission of HIV. The HIV treatment regimens being examined include (1) zidovudine (AZT), (2) zidovudine (AZT) + nevirapine (Viramune), and (3) zidovudine (AZT) + lamivudine (Epivir) + nelfinavir (Viracept). Inclusion and exclusion criteria must be met to participate in this study including, but not limited to, the following: (1) must not have received any HIV medications during the current pregnancy, (2) infants must be 48 hours old or less, and (3) infants must weigh 1500 grams or more. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.
Safety of Tenofovir (Viread) in HIV-infected Pregnant Women and Their Infants

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The purpose of this study is to test the safety and tolerability (how well the body works with the medication) of a single dose of tenofovir (Viread) given during labor to HIV-positive pregnant women and to their newborn infants. Interested individuals must meet extensive inclusion and exclusion criteria including: (1) must be 34 weeks or more (third trimester) into pregnancy at screening and (2) must not participate in any other therapeutic or vaccine perinatal (period of time that is five months before and one month after child’s birth) treatment trials during the current pregnancy, unless given permission by the principal investigators for this study. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.

Prenatal and Postnatal Studies

Contact: Chivon D. Jackson
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The purpose of this study is to collect and study medical information (clinical and laboratory) about pregnant women or new mothers as a way to improve how HIV-positive pregnant women and their children are treated medically. Interested individuals must meet extensive inclusion and exclusion criteria including: (1) must be at least 14 weeks pregnant OR have delivered a live or stillborn infant and are within 14 days of the delivery and (2) must not be currently enrolled in study PACTG 367. Interested individuals should speak with the study contact person for complete inclusion and exclusion criteria.