

Houston HIV/AIDS Clinical Trials Directory

January 2010



The Center for AIDS Information & Advocacy
1407 Hawthorne
Houston, TX 77006
713.527.8219
www.centerforaids.org

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Purpose of the directory

Designed as a tool for the HIV/AIDS community, this directory provides information on clinical trials in Houston.

Before participating in any clinical trial, including trials listed in this directory, please consult with your primary health care provider. For general information on clinical trials, see “What is a clinical trial?” on page 4 of this directory.

If you have questions or comments about the directory, or if you have a study that you’d like to see included in a future edition of the directory, please send email to paul@centerforaids.org.

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What is a clinical trial?

A clinical trial is a research study that helps scientists to better understand a medication, device, procedure, or treatment strategy. In the case of a medication or device, clinical trials are necessary to gain regulatory clearance from the US Food and Drug Administration (FDA).

Clinical trial phases

Some clinical trials are divided into one preclinical and four clinical phases. These trials are used to study potential prescription medications, including HIV medications. Each phase examines a different aspect of the treatment.

- Preclinical – Does the treatment work in the test tube? Is it safe in animals?
- Phase 1 – Is the treatment safe in people? What’s the right dose?
- Phase 2 – Does the treatment do what it’s supposed to do in people?
- Phase 3 – How does the treatment compare to the standard of care?
- Phase 4 – When given to a lot of people, does the treatment cause any unexpected side effects or unexpected toxicity?

Inclusion/exclusion criteria

Clinical trials require participants to have certain characteristics **AND** to not have other characteristics. These characteristics are different for each trial.

“**Inclusion criteria**” are the characteristics an individual MUST HAVE to be considered for participation in a clinical trial. For example, in a trial of an HIV medication, the participant must have HIV.

“**Exclusion criteria**” are characteristics an individual CANNOT HAVE to be considered for participation in a clinical trial. For example, in a trial of an HIV medication, pregnant women are usually excluded until the risk of medication-related birth defects is known.

This directory does *not* list all inclusion and exclusion criteria for each trial. If you are interested in participating in a study, call or email the contact person for a complete list of inclusion and exclusion criteria.

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. Before the trial, during the trial, and after the trial, the principal investigator (PI) of a clinical trial is responsible for meeting the IRB's requirements for the use of human and animal subjects.

For more information on IRBs, visit the Office for Human Research Protections at <http://www.hhs.gov/ohrp/>.

Informed consent

When signing up to participate in a clinical trial, you're presented with an **informed consent form**. Patients under 18 must get their parent's signature to participate in a clinical trial.

The informed consent form should be written in plain language that is easy to understand and should 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 the study.
- Contact information for the IRB responsible for the study AND the clinical trial's PI.

ALSO...

- BEFORE signing the form, you should understand your role in the trial. You may ask for a verbal explanation of the form and the trial. Your questions should be answered by the PI or by a research nurse.

You should get a copy of the form to take home with you, and a copy of any updates to 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 of participating

Some potential benefits of participating in a clinical trial include:

- Access to new medications not yet approved by the FDA
- A better relationship with health care providers (i.e., more time spent discussing your problems or needs)
- The good feeling that comes from helping others. The medical community will gather 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, or hepatitis.

Potential risks of participating

Some potential risks of participating in a clinical trial include:

- The study medication may not work; it might have serious and unexpected side effects; it might compromise your future treatment options.
- Inconvenience and uncomfortable procedures (for example, overnight stays in the hospital and blood draws).
- Loss of income. You may have to take time off from work, and the study may not compensate you.

What else you should know

When participating in a clinical trial, keep these things in mind:

- Participation in a clinical trial is always voluntary. No one can make you take part if you don't want to.
- You can drop out of the trial whenever you want. But you shouldn't sign up for a trial if you think you can't finish it.
- You should still see your regular doctor as scheduled. *Research studies are not a substitute for clinical care.*
- When the trial is over, you should be told about the results, and what the results mean for you.

Clinical trials

Anti-HIV treatments

A5241: Optimizing Treatment for Treatment-Experienced, HIV-Infected People

Contact: Chivon D. Jackson
Phone: 832-824-1319
Address: Texas Children's Hospital, Houston, TX 77030
Email: cdmcmull@texaschildrenshospital.org

The goal of anti-HIV therapy is to prevent HIV from replicating. Long-term control of HIV requires at least two anti-HIV drugs that are active against the virus. Drug resistance is a problem for many treatment-experienced, HIV-infected people. The purpose of this study is to determine the benefit of adding a nucleoside reverse transcriptase inhibitor to a new anti-HIV drug regimen for the suppression of HIV.

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00537394?term=A5241&rank=1>

A5257: Comparative Study of Three NNRTI-Sparing HAART Regimens

Contact: Maria Laura Martinez
Phone: 713-500-6718
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Maria.L.Martinez@uth.tmc.edu

The U.S. Department of Health and Human Services recommends that HIV-infected patients who have never received anti-HIV therapy be treated with a triple drug regimen. The most commonly prescribed and successful regimen contains the medication efavirenz (Sustiva). However, this regimen causes undesirable side effects for some patients. Alternative regimens are needed for these patients.

This study looks at how well different combinations of anti-HIV drugs work to decrease the amount of HIV in the blood (viral load) and allow immune system recovery in people who have never received anti-HIV therapy. This study will also examine drug tolerability and safety for the various drug combinations.

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00811954?term=A5257&rank=2>

A5260s: Impact of Antiretroviral Therapy on Metabolic, Skeletal, and Cardiovascular Parameters

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

This substudy of A5257 looks at the effects of new regimens on metabolic, skeletal, and cardiovascular factors.

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00851799?term=A5260s&rank=1>

A5241: Optimizing Treatment for Treatment-Experienced, HIV-Infected People

Contact: Maria Laura Martinez
Phone: 713-500-6718
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Maria.T.Insignares@uth.tmc.edu

The goal of anti-HIV therapy is to prevent HIV from replicating. Long-term control of HIV requires at least two anti-HIV drugs that are active against the virus. Drug resistance is a problem for many treatment-experienced people. The purpose of this study is to determine the benefit of adding a nucleoside reverse transcriptase inhibitor (NRTI) to a new anti-HIV drug regimen for the suppression of HIV.

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00537394?term=A5241&rank=1>

A5256: Safety and Effectiveness of Addition of Maraviroc to ART Regimens in HIV-Infected Adults With Suboptimal CD4 T-Cell Count Recovery Despite Sustained Virologic

Contact: Martine Diez
Phone: 713-500-6719
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Martine.M.Diez@uth.tmc.edu

Some HIV-infected individuals with low viral load on antiretroviral therapy do not have increased CD4 counts and remains at risk for clinical progression of HIV. The purpose of this study is to assess whether adding maraviroc to a stable ART ...

regimen will result in an improved immune response in individuals with a limited CD4 response despite sustained virologic suppression.

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00709111?term=A5256&rank=1>

A5262: Safety and Effectiveness of Raltegravir and Darunavir/Ritonavir in Treatment-Naive HIV-Infected Adults

Contact: Martine Diez
Phone: 713-500-6719
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Martine.M.Diez@uth.tmc.edu

The purpose of this study is to assess the effectiveness and safety an antiretroviral therapy (ART) regimen consisting of raltegravir (RAL) and darunavir (DRV)/ritonavir (RTV) as first-line therapy in treatment-naïve participants.

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00830804?term=A5262&rank=1>

START: Strategic Timing of Antiretroviral Treatment

Contact: Maria Laura Martinez
Phone: 713-500-6718
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Maria.L.Martinez@uth.tmc.edu

The purpose of this randomized study is to determine whether immediate initiation of antiretroviral treatment is superior to deferral of antiretroviral treatment until the CD4+ cell count declines below 350 cells/mm³ in terms of morbidity and mortality in infected people who are antiretroviral naive with a CD4+ count above 500 cells/mm³.

Behavior and HIV

An Innovative Telephone Intervention for HIV Positive Smokers

Contact: Netri Mehta
Phone: 713-745-4479
Address: University of Texas – MD Anderson Cancer Center,
Houston, TX 77230
Email: nmehta@mdanderson.org

The purpose of this study is to assess a smoking cessation intervention targeted to HIV positive patients.

Children

In association with the International Maternal Pediatric Adolescent AIDS Clinical Trials Group, the Adolescent Trials Network, and the AIDS Clinical Trials Group, the Baylor College of Medicine runs studies for children, teenagers and adults with HIV. Funding is available for transportation of HIV-infected children and their caregivers to Houston to participate in clinical research.

A list of studies for children can be found at:
<http://bayloraid.org/houston/clinicaltrials/shtml>

For more information, call 832-824-1319.

Co-conditions and opportunistic infections

A5240: Safety of and Immune Response to the Human Papillomavirus (HPV) Vaccine in HIV-Infected Women

Human papillomavirus (HPV) is the most common sexually transmitted disease in the world. HPV infection can cause genital warts and certain cervical problems, including cervical cancer. HPV infection may be more severe and harder to treat in HIV-infected people. The purpose of this study is to determine whether the quadrivalent HPV vaccine is safe, tolerable, and effective in producing antibodies to HPV in HIV-infected women.

Contact: Francisco Mora
Phone: 713-500-7698
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Francisco.Mora@uth.tmc.edu

Contact: Chivon Jackson-McMullen
Phone: 832-824-1339
Address: Texas Children’s Hospital, Houston, TX 77030
Email: cdmcmull@texaschildrenshospital.org

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00604175?term=A5240&rank=1>

A5247: Live Zoster Vaccine in HIV-Infected Adults on Antiretroviral Therapy

Herpes zoster, or shingles, is the result of a viral infection that causes a painful skin rash, usually in older people or people with suppressed immune systems like those infected with HIV. The ZOSTAVAX vaccine has been shown to reduce the number of infections and symptoms of herpes zoster infection in people over the age of 60. The purpose of this study is to test the safety and tolerability of ZOSTAVAX in HIV-infected adults.

Contact: Maria Laura Martinez
Phone: 713-500-6718
Address: University of Texas – Houston School of Medicine, Houston, TX 77030
Email: Maria.L.Martinez@uth.tmc.edu

For more information, see:

<http://www.clinicaltrials.gov/ct2/show/NCT00851786?term=A5247&rank=1>