

HIVresource

A GUIDE TO CLINICAL RESEARCH IN THE SAN FRANCISCO BAY AREA

INSIDE: San Francisco Bay Area clinical research opportunities

Canakinumab, an antibody therapy, found to reduce HIV inflammation

In a very small study of people living with HIV, a one-time antibody treatment significantly reduced the type of inflammation that can lead to heart attacks and other cardiovascular problems—a leading health concern for people living, and aging, with HIV. Priscilla Hsue, MD, FACC, a physician at the University of California San Francisco, presented these findings at the Conference of Retroviruses and Opportunistic Infections in February.

This study, and other studies that investigate therapies to reduce HIV-associated inflammation, will be increasingly important as people living with HIV are able to live longer. Even people with well-controlled HIV are at greater risk of developing cardiovascular disease—and increased inflammation is likely to blame. Antiretroviral therapy can decrease inflammation, but does not eliminate it completely.

“I think it’s remarkable that a small number of patients, after just getting a single dose of canakinumab, were able to demonstrate a very significant and profound reduction in inflammation as well as a reduction in arterial inflammation,” said Hsue.

The treatment used in the study was a monoclonal antibody, named canakinumab, that binds and blocks an IL-1 β receptor on cytokines (which is part of a cell signaling pathway upstream in a pathway that leads to inflammation). The ten participants in the study received one single dose of canakinumab (150 mg) under the skin.

Canakinumab significantly reduced a marker of inflammation, interleukin-6 (IL-6), by 24% after four weeks. The therapy reduced IL-6 by 30% after eight weeks. The antibody treatment also significantly reduced two additional markers of inflammation. High sensitivity C-reactive protein (hsCRP) was reduced by 41% after eight weeks and soluble CD163 was reduced by 9% after eight weeks.

This study is one of the first to show that an immune-based therapy can profoundly reduce markers of inflammation in people with HIV—and importantly, in people with already well-controlled HIV. (Everyone in the study had been living with HIV for over 20 years and had good viral control, i.e., were on antiretrovirals with an undetectable viral load.) The antibody therapy did not have any negative effects on viral control or CD4 count, and was well-tolerated by people in the study.

Canakinumab is already approved by the FDA as a treatment for other conditions, but further research is needed to demonstrate if it is safe and effective at reducing inflammation for people living with HIV. A study is currently underway, said Hsue, of 100 people randomized to a placebo-controlled study. People receiving the investigational drug will get two doses, and will be followed for a total of 36 weeks.

Read more HIV research on www.betablog.org.

California cancels contract with ADAP administrator; HIV advocates hopeful for a better system

In a move to fix ongoing service provision problems by the AIDS Drug Assistance Program (ADAP), the California Department of Public Health announced that they have terminated a contract with ADAP administrator A.J. Boggs, effective March 31. This decision comes after continuing complaints from ADAP clients and enrollment workers, and pressure from HIV advocacy groups and key members of the legislature concerned about the frustrations and difficulties that people living with HIV have been experiencing with the ADAP system.

Enrollment workers and HIV advocates are optimistic about the decision, and hopeful that the change will bring about much-needed improvements to the ADAP system.

“We are thankful that the State Office of AIDS has responded to our requests for change,” said Courtney Mulhern-Pearson, director of state and local policy at San Francisco AIDS Foundation. “The last seven months have been extremely disruptive for clients trying to obtain their medication through ADAP, and many of them have been denied coverage since the switch to A.J. Boggs. We want to make sure that people living with HIV in our state are never without coverage or care for the medications they need.”

DRUG PIPELINE

New HIV drug research presented at CROI 2017

Ibalizumab, a humanized monoclonal antibody that protects immune cells from HIV rather than attacking HIV directly, helped 43% of treatment-experienced participants achieve viral suppression after 24 weeks.

PRO-140, a long-acting monoclonal antibody blocking the CCR5 receptors on CD4 cells, demonstrated potent antiviral activity with 81% of participants maintaining viral suppression for more than 40 weeks.

Doravirine, a new NNRTI, helped 84% of people sustain viral suppression after 48 weeks on treatment.

Bictegravir, an investigational integrase inhibitor, helped 97% of people achieve viral suppression after 24 weeks and 48 weeks.

GS-CA1, a new type of drug called a capsid inhibitor, is currently being investigated as a potent, long-acting therapy.

Read more on www.betablog.org.

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Clinical Research Opportunities

Studies are listed with brief descriptions only. Additional inclusion and exclusion criteria may apply. For more information, please contact the study site directly.

Bridge HIV

San Francisco Department of Public Health
25 Van Ness, Suite 100
San Francisco, CA 94102

- **Antibody Mediated Prevention (AMP):** The AMP Study is a groundbreaking new research study that tests the idea of giving people antibodies to see if they will protect people from getting infected with HIV. Must be HIV negative, healthy and age 18–50. May be a male or transgender person who has sex with men. Compensation up to \$100/visit. Visit www.PowerToPreventHIV.org or call 415-437-7485.
- **HIV vaccine study:** Study evaluating the safety and dosage of HIV vaccines. Must be HIV negative, healthy and age 18–50. May be male, female, or transgender. Compensation is \$50–\$75/visit. Visit www.PowerToPreventHIV.org or call 415-437-7485. You cannot get HIV from the study vaccine.
- **Pre-exposure prophylaxis (PrEP) study:** Study testing the safety of a pill and a long-acting injectable (a shot). Must be HIV-negative, healthy and age 18+. May be a male or transgender woman who has sex with men. Visit www.PowerToPreventHIV.org or call 415-437-7485. New Study.
- **Health tech study for men:** Bridge HIV is looking for young men who have sex with men between 18-35 years old to participate in interviews to provide feedback on a new mobile app. If eligible, you will be compensated up to \$75 per visit. Please call or text us at 415-385-3973 to enroll today! All information is kept strictly confidential.
- **Get paid to test at home & help fight HIV!** Bridge HIV is recruiting Black and Latino men, 18-35 years old, for a home HIV & STI testing research project. If eligible you can earn up to \$175 for participating. Call or text us at 415-385-3973 or visit helpfighthiv.org/volunteer to enroll today. All information is kept strictly confidential.

East Bay AIDS Center (EBAC)

3100 Summit Street, 2nd Floor
Oakland, CA 94609
http://www.altabatessummit.org/clinical/aids_scvs.html
510-869-8400

- **GS-US-412-205:** Study to test an experimental drug for the prevention of HIV infection in HIV-negative men who have sex with men and transgender women who have sex with men. Participants will receive either the experimental drug (emtricitabine/tenofovir alafenamide, F/TAF), or Truvada. The study will last about 144 weeks with at least 17 clinic visits. \$60/for each completed visit. New Study.
- **HPTN 083:** Study to test the safety and efficacy of injectable cabotegravir compared to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) for pre-exposure prophylaxis (PrEP) in HIV-negative men who have sex with men and transgender women who have sex with men. Study lasts at least 1.5 years and up to 4.5 years, with approximately 25 – 57 clinic visits. Payment of \$20 for the screening visit, \$75 for the enrollment visit, and \$50 for follow-up visits.

Kaiser Clinical Trials Unit

4141 Geary Boulevard, Suite 219
San Francisco, CA 94118
Miki.mettinger@kp.org, 415-833-3223
Susan.F.Kirk@kp.org, 415-833-3480

- **TMB-311:** A phase 3, multi-center, expanded access study of Ibalizumab plus an optimized background regimen (OBR) in treatment-experienced patients infected with multi-drug resistant (MDR) HIV-1.
- **GS-US-412-2055:** A phase 3, randomized, double-blind study to evaluate the safety and efficacy of emtricitabine and tenofovir alafenamide (F/TAF) fixed-dose combination once daily for pre-exposure prophylaxis in men and transgender women who have sex with men and are at risk of HIV-1 infection. New Study.

Metropolis Medical Group

815 Hyde Street, Suite 301
San Francisco, CA 94109
www.metropolismedical.net
415-292-5477 ext. 487

- **Flair Study (GSK 1265744):** Study for people with HIV who have never been treated before (“treatment naïve”). Treatment will be provided with an all-injectable regimen (i.e. no pills), with monthly injection of rilpivirine and the investigational integrase inhibitor cabotegravir. Injections are given in the clinic. The study is started with a lead-in pill regimen for 5 months. Long-term evaluation of efficacy, safety, and tolerability. Compensation is \$75 per study visit. New Study.
- **Atlas Study (GSK 201585):** Switch from any standard HIV pill regimen to an injectable regimen for the treatment of HIV: Monthly injection of rilpivirine and the investigational integrase inhibitor cabotegravir for ongoing suppression of HIV. Injections are given in the clinic. Participants need to be on their 1st or 2nd HIV regimen and not have resistance to any medications provided. Long-term evaluation of efficacy, safety, & tolerability. Very popular study at our site, and currently only looking for women to participate. \$75 per study visit. New Study.
- **911 study:** Early investigation of a new HIV “maturation inhibitor.” 10-day study to investigate potency and drug levels of this new compound. Daily blood draws and 2 overnight stays in the clinic required. Study compensates for participation with \$1300. We are looking for men or women with HIV but no other medical conditions. New Study.
- **Sword:** Switch study to a “nuc-sparing” regimen, containing Tivicay and Edurant, once/day. People with HIV qualify, if they are on their first or second HIV treatment and have an undetectable viral load. \$75 per study visit, this study will be ongoing for 3 years and provides HIV medications.
- **Amber Study (TMC 114IFD3013):** People with HIV, but never been treated (“treatment-naïve”) and detectable viral load will start with an HIV regimen of Reyataz/Norvir, and Truvada or an investigational one-tablet-a-day regimen containing darunavir, cobicistat, emtricitabine and tenofovir alafenamide (TAF). \$75 per study visit.

Optimus Medical Group

Shawn K. Hassler, MD
870 Market St, STE 600
San Francisco, CA 94102
(415) 423-4055

- Are you a high risk male, or transgender female who is HIV negative and having unprotected sex? If so you may be eligible to participate in a Phase 3 study to evaluate the safety and efficacy of F/TAF fixed-dose combination once daily for pre-exposure prophylaxis in men and transgender women who have sex with men and are at risk of HIV-1 infection. Volunteers receive \$50 per visit, free PrEP, labs, STD testing, ECGs and medical care for up to 3 years from a board certified HIV specialist in San Francisco. Please call 415-397-0700 or email us today at info@studyops.com.

San Francisco AIDS Foundation

Tessa Swigart, Study Coordinator
tswigart@sfaa.org
415-437-3409
470 Castro Street, San Francisco

- The DISCOVER study is a trial of a new investigational medication for PrEP called FTC/TAF (emtricitabine/tenofovir alafenamide). The medication was approved for HIV treatment last year, and is now being evaluated as PrEP. When used for HIV treatment, FTC/TAF had less effect on bone mineral density and kidney function compared with other HIV treatments. This study will evaluate whether FTC/TAF is as safe and effective as FTC/TDF (Truvada) for PrEP.
- Every participant in the DISCOVER Study will receive an active medication for PrEP (either the FDA approved FTC/TDF or the investigational FTC/TAF). Every participant will receive HIV testing, testing and treatment for sexually transmitted infections, screening for hepatitis C infection, and screening for hepatitis B infection (and vaccination if needed). The active medication and the study medication and study related procedures and tests will be provided at no charge to the study participants and study participants will receive a stipend of \$75 per visit to help compensate for their time and transportation.

Substance Use Research Unit

San Francisco Department of Public Health
25 Van Ness Suite 500
San Francisco, CA 94102

- M2.0: A study testing whether taking a medication (mirtazapine) reduces meth use in men who have sex with men. Study includes weekly substance use/risk reduction counseling. Eligible participants are compensated up to \$595 over the course of the study. To see if you are eligible, please call us at 415-437-6319. Email: m2.study@sfdph.org; Website: www.m2study.org.
- Say When: A study for gay and bisexual men testing whether a medication (oral naltrexone) taken on an as-needed basis can help to reduce alcohol use. This study is open to HIV-positive or HIV-negative people. Eligible participants are compensated up to \$664 over the course of the study. To see if you are eligible, please call us at 415-437-6333. Email: say.when@sfdph.org; Website: www.saywhensf.org.
- Bye-C: A study that is open for all people who are hep-C positive and have never had treatment. We are exploring two different dosing regimens (daily observed treatment and unobserved dosing 20/10) with the medication Harvoni, which has a 92-100% cure rate for the virus. Please call us at 415-437-6325.

UCSF, Division of Hematology/Oncology
513 Parnassus Ave, S1459
San Francisco CA 94143
415-476-9547

- UCSF study of healthy HIV-positive people who are not on therapy: The Jay Levy lab is looking for HIV-infected individuals who are healthy and not on therapy to be part of a research project examining their natural immune response against HIV. Those interested will be interviewed by phone and then seen by Dr. Levy and his group. Please send an email to Bao.Sit@ucsf.edu.

UCSF, Anal Neoplasia Clinic

1701 Divisadero Street, Suite 480
San Francisco, CA 94115

- Anal cancer rates are rising among people living with HIV. The ANCHOR study's goal is to find the best way to prevent anal cancer among HIV+ men and women ≥ 35 years old. Study visits are every 6 months for at least 5 years. Participants are compensated \$100 per visit. For more info go to anchorstudy.org or call 415-353-7443.

UCSF, Mount Zion, ANCRE Clinic

1701 Divisadero Street, Suite 480
San Francisco, CA 94115
Cristina Brickman, MD; Marya Krogstad, RN
(415) 353-7527, marya.krogstad@ucsf.edu

- AMC 088: A randomized, open label phase III study of treatment of high-grade anal squamous intraepithelial lesions (HSIL) in HIV+ men and women. This study will compare the efficacy between 2 different self-applied creams in the treatment of anal HSIL with observation only. Eligible volunteers with HSIL are randomized to one of 3 groups: Imiquimod cream treatment; Effudex cream treatment; or observation only. The observation group is offered randomization to a treatment group at week 24 if HSIL persists. Study lasts just under a year with a total of 7 to 11 visits. Compensation is provided. Study open to people with HIV of all genders and ages. People who have used these creams previously are excluded. Contact Rachel Silverstein at 415-353-7443 or rachel.silverstein@ucsf.edu.

UCSF Research Center

387 Golden Gate Ave, San Francisco
415-298-3108

- Hepatitis C cure study for people who inject drugs: participants provided with hepatitis C treatment and either one of two care models. People who are over age 18, who inject drugs, and are infected with hepatitis C are eligible for the study. Participants are provided financial compensation and transportation assistance to all study visits.

UCSF, Zuckerberg San Francisco General Hospital, 995 Potrero Ave, Building 80, Ward 8 San Francisco, CA 94110
Dan Berner, 415-476-4082 x 556 or Daniel.Berner@ucsf.edu

HIV studies:

- ATLAS: Switch to monthly intramuscular cabotegravir/rilpivirine for patients on stable ART. HIV-positive people well-controlled on first or second ART regimen who are willing to switch to monthly intramuscular CAB/RIL. Patients will be randomized to early switch (after 1 month of oral CAB/RIL) or delayed switch after 48 weeks. All participants will be able to receive intramuscular ART.
- A5315: Safety and tolerability study of Romidepsin for people taking ARVs. Participants must be taking ART that includes raltegravir, dolutegravir, or efavirenz-based regimen, viral load less than 50 for past 12 mos, CD4 over 300, men and non-pregnant women over 18 years.
- A5332: "REPRIEVE" study to see if pitavastatin can prevent heart disease and related deaths. Participants must be HIV+, 40-75 years, on ARVs for at least 6 mos, CD4 over 100, no history of cardiovascular disease, and not currently using a statin drug.
- A5336: The ORALJAK2-STAT inhibitor Ruxolitinib to evaluate impact on immune activation and inflammation. This phase I study will enroll HIV-positive people with CD4 over 350 on suppressive ART for at least 2 years. Enrollees will be randomized to open-label oral Ruxolitinib vs. no treatment for 5 weeks and followed for a total of 12 weeks.
- A5345: Intensely Monitored Antiretroviral Pause. This study will intensely monitor enrolled patients who stop ART during the study. They will be intensely monitored for viral rebound and to identify biomarkers associated with virologic control and rebound. This study is NOT open to individuals who are currently off ART; must be stable on ART for at least 2 years and willing to be monitored closely during a supervised treatment pause.

HIV/hepatitis C coinfection studies:

- A5320: Observational cohort for HCV patients who have recently completed an HCV clinical trial in last 12 months containing a Direct Acting Agent (DAA) (HIV infected or uninfected). We are looking for patients who have participated in recent HCV treatment containing at least one DAA agent through a clinical trial setting (with or without interferon or ribavirin). HIV infection not required.
- A5329: All oral, interferon-free triple therapy with Viekira Pak for HIV/HCV coinfecting patients with hepatitis C genotype 1. Will enroll both treatment naive and experienced (including prior Sofosbuvir failures). Liver biopsy not required. ART permitted includes darunavir/r, atazanavir/r, dolutegravir, raltegravir, with tenofovir, abacavir, 3TC/FTC.
- Multiple other HIV studies and hepatitis C treatment studies available, including interferon-sparing regimens enrolling hepatitis C monoinfected and HIV/HCV coinfecting and HCV. For more information and to see if you may qualify contact Dan at 415-476-4082 x556 or Daniel.Berner@ucsf.edu.

Zuckerberg San Francisco General, Positive Health Program

995 Potrero Ave, Building 80, 4th Floor
San Francisco, CA 94110

- GS-9620: A randomized, double-blind study a TLR-7 agonist to determine safety and tolerability of GS-9620 to reduce the viral reservoir. 50 - 70 visits over 12 - 17 mos. Compensation provided. Call 415-476-4082, x139, or x104; email Rebecca.Hoh@ucsf.edu or Viva.Tai@ucsf.edu. New Study.
- HIPSTER: A group of studies using scanning techniques to learn how & where HIV persists in the body. 1-2 screening visits and 1 visit for PET/MRI scan. Enrolling HIV+ with CD4 over 300, and documented undetectable viral load for more than 12 months. Compensation provided. Call 415-476-4082, x139, or x104; email Rebecca.Hoh@ucsf.edu or Viva.Tai@ucsf.edu.
- DARE: A group of studies learning how & where HIV persists in the body. Multiple visits to measure

HIV viral reservoirs. Enrolling either 1) newly infected or 2) those not taking ART or 3) continuously ART-suppressed more than 12 mos. Compensation provided. Call 415-476-4082, x139, or x104; email Rebecca.Hoh@ucsf.edu or Viva.Tai@ucsf.edu.

- Flu Vaccine Study: observational study assessing immune response to standard flu vaccine. 3-5 visits. Enrolling age 40-65 and HIV+ and HIV-negative. Seasonal flu vaccine & compensation provided. Call 415-476-4082 x155; email Heather.Hartig@ucsf.edu.
- GALT Study: assessing HIV damage to the immune system. Screening visit, rectal biopsy, and blood draws. Enrolling HIV+ and HIV-negative. Compensation provided. Call 415-476-4082 x140; Montha.Pao@ucsf.edu.
- Leukapheresis study: Collection of white blood cells to determine how much HIV is in different types of cells. 1-2 screening visits and a 3-4 hour white blood cell collection. Enrolling HIV+ and HIV-negative. CD4 count >300 with excellent venous access. Compensation provided. Call 415-476-4082 x139; Rebecca.Hoh@ucsf.edu.
- Lymph node biopsy study: A study seeking to measure and analyze HIV viral reservoir in lymph nodes. 1-2 screening visits, a lymph node biopsy & blood draws. Enrolling HIV+ and HIV-negative. Compensation provided. Call 415-476-4082, ext 144; Marian.Kerbleski@ucsf.edu.
- SCOPE Study: Observational study recruiting (1) natural controllers (HIV+ with VL <10,000 copies/mL & not taking ARVs), (2) people not taking ARVs, (3) ARV-suppressed at least 12 months, or (4) HIV-negative controls. Interviews & blood draws 2-3 times per year. Compensation provided. Call 415-476-4082 x140 or x 155; email Montha.Pao@ucsf.edu or Heather.Hartig@ucsf.edu.
- Treat Acute: Rapid ARV treatment for recent HIV infection. Must be 18 years or older, within 4 months of estimated HIV infection date, and ART-naïve (prior PrEP use okay). Other criteria apply. Contact 415-476-9296 x 325; Lisa.Harms@ucsf.edu.