UCSF/SFGH HIV, ID and GLOBAL MEDICINE DIVISION & AFFILIATES OPEN ADULT STUDIES (March 2016)

Study	Contact	Design	Basic Criteria
ACUTE / EARLY INFECTION STUDIES			
OPTIONS: Acute and early HIV pathogenesis	(415) 502-8100 Lisa	Observational study of latent viral reservoir	Acute or early HIV infection (< 6 months). Treatment naïve or very recent onset.
ANTIRETROVIRAL TREATMENT STUDIES			
RADL: A cross-sectional study to assess how antiretroviral drug levels in lymphoid tissues differ between antiretroviral regimens and whether differences in antiretroviral drug levels are associated with the size of viral reservoir.	(415) 476-4082 Sophie x104	2-3 visits: Questionnaire, blood draw, GALT and lymph node biopsies.	1. On first and only ARV regimen of: a. raltegravir & emtricitabine/Tenofovir or b. atazanavir, ritonavir, & emtricitabine/Tenofovir or c. darunavir, ritonavir, & emtricitabine/tenofovir 2. ART suppressed for ≥1 year 3. >90% adherence to therapy within the preceding 30 days
IMMUNOLOGIC STUDIES			
Effects of HAART on Immune Diversity: How quickly is the diversity of the T cell receptor repertoire restored after beginning HAART?	(415) 476-4082 Montha x140 Joy x155 Becky x139	Questionnaire and blood draw. *Once before starting HAART. *Two, four and six months after starting HAART	HIV+, any CD4 and viral load, ARV treatment naive, now starting HAART (any regimen)
COMPLICATIONS AND CO-INFECTION STUDIES			
AMC 072: Gardisil to prevent HPV Infection in Young HIV+ Males Who have Sex with Males	(877) 827-3222 Fred	Open-label evaluation of evaluation of Gardisil in HIV+ young men	HIV+ men ≤ 26 years old. Either stable HIV meds for 3 months or not receiving HIV meds and CD4 count ≥ 350 with no plans to start meds for 6 months
Community-Associated MRSA	(415) 443-MRSA Joann Volinski Michele Downing	Randomized double-blind trial comparing CLINDA, TMP-SMX, or placebo for uncomplicated skin and soft tissues infections caused by CA-MRSA	single abscess site with at least 2 of: *erythema *tenderness *local warmth *purulent drainage *induration. No diabetes. No antibiotics in last 14 days, HIV-Neg or HIV+, CD4>200 in last 6 months, BMI ≤ 40

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A5332: A aandomized Trial to Prevent Vascular Events in HIV – REPRIEVE	(415) 476-4082 Ext. 358	In this study, people between the ages of 40 and 75 with HIV will be randomized to take pitavastatin OR a placebo to see if pitavastatin can help prevent heart disease and death in people who are taking HIV medication.	HIV+ patients aged 40-75, on ART without a current indication for a statin and no history of coronary vascular disease. Patients will be randomized to placebo vs. 4 mg of pitavastatin. CD4 cell count > 100, on ART x 6 months on more. Hepatitis B and/or C ok, as long as not cirrhotic
B-HIVE: Bococizumab HIV Evaluation Study	(415) 206-5145 Sophia	Radomized clinical trial to evaluate the impact of bococizumab on lipid-lowering in adults with HIV infection. Study is 58 weeks long with 10 visits and bi-weekly self-injections of study drug.	HIV+ men & women >40 years old with undetectable VL x 1 year, CD4 > 50, and known cardiovascular disease or at least 1 risk factor (smoking, dyslipidemia, hypertension, DM2)
HEPATITIS STUDIES			
ACTG 5320: 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 infected)	(415) 476-4082 Ext. 358	We are looking for patients who have participated in recent HCV treatment containing at least one Direct Acting Agent for hepatitis C treatment through a clinical trial setting (with or without interferon or ribavirin). Direct acting agents include polymerase inhibitors (such as sofosbuvir), NS5A inihibitors (such as daclatasvir, ledipasivir), and protease inhibitors (such as simeprevir)	• HIV+/Hep C co-infected men and women ≥18 years of age OR HCV mono-infected men and women ≥18 years of age • Completed treatment for Hep C in the last 12 months as part of a clinical trial, whether cured or not cured. • Not currently on Hep C treatment
ACTG 5327: Treatment of Acute HCV with HIV coinfected patients Sofosbuvir + Ribavirin for 8-12 weeks in. All HCV GENOTYPES	(415) 476-4082 Ext. 358	HIV patients coinfected with HCV (any genotype) with acute HCV (defined as first HCV related laboratory abnormalities occurring the past 6 months) will receive 12 weeks of sofobuvir+ ribavirin. A subsequent cohort will receive 8 weeks of sofosbuvir/ribavirin if the first cohort attains a high cure rate. No biopsy required.	• ≥ 18 years of age • acute HCV infection within the last 6 months or recent re-infection of HCV • Currently not on any antiretroviral therapy (ART) or on stable ART for at least 8 weeks prior to study entry. • Cannot have an active or acute AIDS-defining infection, other active, serious infections or a serious medical condition that would interfere with study participation

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Study	Contact	Design	Basic Criteria
Multiple studies enrolling HIV-HCV coinfected patients	(415) 476-4082 Ext. 358	Multiple treatment studies, including interferon-sparing regimens	Call to see what is currently available and if you may qualify.
ANTIRETROVIRAL INTENSIFICATION, INFLAMMATION REDUCTION, AND HIV ERRADICATION			
ACTG5315: Safety and tolerability study with a single dose of Romidepsin (RMD) for people taking antiretroviral drugs with an undetectable viral load	(415) 476-4082 Ext. 358	This study is to look at a one-time infusion of Romidepsin (RMD) to make sure it is safe, easy to take, and to see if it can wake up the hidden or sleeping HIV virus in people receiving HIV treatment. Each person will go into one of three groups (depending on when you enter this study) and will be assigned to one of three doses. Each group will enroll 15 subjects: 12 will receive RMD and 3 will receive a placebo (salt water solution) that does not contain RMD.	• Taking ART that includes a raltegravir, dolutegravir, or efavirenz-based regimen • HIV-1 RNA (viral load) < 50 for past 12months • CD4+cell count > 300 • Men and non-pregnant women age >18 years
Lisinopril to reduce lymphoid fibrosis and size of latent reservoir in ARV-treated patients	(415) 476-4082 Kara x104	36 week study placebo-controlled study evaluating ACE-inhibitor. GALT and lymph node biopsies	Stable ARVs > 12 months, undetectable. No anticoagulant therapy
ACTG A5314: Methotrexate study to evaluate the effect of low dose methotrexate on markers of cardiovascular disease and inflammation.	(415) 476-4082 Ext. 358	Randomized, double blind, placebo controlled clinical trial	> 40 years old, On ART and HIV RNA below limit of quantification ≥ 24 weeks, CD4 cell count > 400, with moderate to high cardiovascular disease risk (known coronary or vascular disease, DM2, or CVD risk factors)
A5325: A Prospective Randomized Controlled Study to Evaluate the Effect of Isotretinoin on Immune Activation Among HIV-1 Infected Subjects with Incomplete CD4+ T Cell Recovery on Suppressive ART	(415) 476-4082 Ext. 358	Open label, randomized, controlled, site-limited, two-arm (study drug vs. no study drug) phase II trial	HIV+, ART therapy for at least 12 months prior to entry, HIV-1 RNA below the lower limit of detection, CD4 <350, no active hepatitis B or C infection
A5342: A Phase-I Study to Evaluate the Safety, Tolerability, and Effect of a Human Monoclonal Antibody, VRC-HIVMAB060-00AB (VRC01), on Markers of HIV Persistence in ART-treated, HIV-infected Adults	(415) 476-4082 Ext. 358	A Phase I study of monoclonal antibody to evaluate impact on HIV reservoir	HIV+ patients, well controlled on ART x at least 2 years with HIV RNA < limit of detection, CD4 > 200

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The Canakinumab Study: Effect of IL-1β Inhibition on Inflammation and Cardiovascular Risk	(415) 206-5801 Danny	Radomized clinical trial to study the impact of canakinumab on inflammation reduction and improvement in heart health in adults with HIV infection. Study is 9 months with 12 visits.	HIV+ men & women >40 years old, on ART with undetectable VL x 1 year, CD4 > 400, and known cardiovascular disease or at least 1 risk factor (smoking, dyslipidemia, hypertension, DM2)
OBSERVATIONAL AND OTHER STUDIES			
SCOPE: Observational study enrolling HIV+ ARV naïve, long-term non-progressors, elite controllers, and long-term suppressed on ARV. Also enrolling HIV-negative patients	(415) 476-4082 Becky x139 Montha x140 Joy x155	Questionnaire, blood draw, saliva collection every 2-4 months	**Any of the following (other criteria apply):** 1. ARV-continuously suppressed >12 years 2. Treatment-naïve: any CD4 & viral load 3. Elites: VL<2000, not on ARVs 4. LTNP: HIV+>10yrs, CD4>500, no ARV 5. HIV negative
DUO Project-Phase 3: Observational study about HIV treatment among male same-sex couples	(415) 597-9322 or (877) 386-6292	2-hour computerized interviews on medication attitudes and behaviors of men in same-sex couples. 3 interviews and, if HIV+, 2 blood draws	Male same-sex couples. One or both partners currently taking ARVs. 18 years of age or older
STAYING WELL PROJECT: Effects of meditation-based stress management and education on physical health and well-being	(415) 353-9744 Patty or Michael	8 week meditation-based stress management or education sessions; questionnaire; blood draw; physio monitoring x4; saliva collection x3.	No current ARVs, CD4 > 250, HIV RNA > 100
IMPAACT P1025: Observational adherence study in pregnant HIV+ women	(415) 206-8919	Prenatal/Postnatal Studies of Interventions for Prevention of Mother-To-Child Transmission of HIV	HIV+ women at least 14 weeks pregnant Currently receiving care at an IMPAACT site
Exposed Seronegatives	(415) 502-8100 Ed or Lisa	GALT, Blood draws, and Counseling	Men: URAI w/ ≥10 men in last 12 mos, or repeated unprotected sex w/ HIV+ viremic ptnr (serodiscordant couples are welcome)
DISCO: survey of HIV-negative women seeking pregnancy with HIV-positive male partners	(415) 206-3658	Online anonymous survey: https://www.surveymonkey.com/s/D5YQ77L	Desire for pregnancy Reproductive age HIV-negative women HIV-positive male partner

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DARE: seeking to identify how and where HIV persists despite long term antiretroviral therapy. http://delaneydare.org	Steve Deeks Study Group (415) 476-4082 Becky x139 Marian x 144 Kara x 104	Multiple visits to measure & analyze the HIV viral reservoir. Visits may include blood draws, leukapheresis, and tissue biopsies (GALT and lymph node).	Documented continual ARV-suppression, VL<40 x last 5 years, CD4>400. No immunomodulator use. **Other criteria apply**
Disulfiram: to determine if disulfiram (Antabuse) is safe and well tolerated and if it has a role in helping clear HIV from the body	Steve Deeks Study Group (415) 476-4082 Becky x139 Marian x 144	1 month study with 12 blood draws and 3 doses of open label disulfiram.	Documented continual ARV-suppression, VL<40 x last 3 years, CD4>350. Able to abstain from alcohol during study. No immunomodulator use. **Other criteria apply**
ACTG A5321: Observational study evaluating HIV reservoirs	(415) 476-4082 Ext. 358	Evaluation for up to 5 years in a longitudinal observational study	Basic Criteria: HIV infected patients who 1) started ART within 45 days of diagnosis of acute HIV or 2) who were elite controllers (HIV RNA <500 copies) at time of ART initiation and now are virologically suppressed on ART
STARTING THERAPY: Effects on Central Nervous System of HIV treatment initiation	(415) 206-4328 Alex	Interview, neurological testing, blood draw, spinal taps and/or MRI scans in longitudinal observational study	HIV+ with CD4 count < 400 starting antiretroviral therapy under guidance of primary provider
STABLE THERAPY: CNS study of HIV viral burden in patients on stable antiretroviral therapy	(415) 206-4328 Alex	Interview, neurological testing, blood draw, spinal taps and/or MRI scans in longitudinal observational study	HIV+ on ART for >12 mon with evidence of undetectable VL, CD4 <300 before initiating ART
Shaved heads study for ARV detection	(415)-476-4082 Ext. 138 Steve May	Shaving your head for science: one time-donation ($250 reimbursement)	HIV-positive on any antiretroviral regimen x 6 months, undetectable VL x 6 months