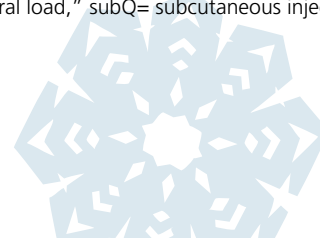


UCSF Positive Health Program (PHP)

OPEN ADULT HIV STUDIES – WINTER 2008

ACUTE / EARLY INFECTION STUDIES			
STUDY	CONTACT	DESIGN	BASIC CRITERIA
OPTIONS: Acute and early HIV pathogenesis	502-8100 Ed or Lisa	Observational study of latent viral reservoir	Acute or early HIV infection (< 6 months). Treatment naïve.
AIN503: Early HAART vs. no HAART – comparison of viral setpoints after treatment interruption.	514-0550 Deborah x330	Kaletra + Truvada vs. no treatment	Early HIV infection (< 6 months) but not acute. Treatment naïve. HIV RNA > 500, CD4 > 350 Willingness to stop or defer ARVs
CNS PHI: Effects of acute and early HIV-infection on the nervous system	206-4238 Evelyn	Interview, neurological testing, blood draw, options for spinal taps and/or MRI scans in longitudinal observational study	Acute or early HIV infection (< 6 months)
NUCLEOMAXX STUDY: Effects of uridine supplementation in patients on regimens containing AZT or D4T	206-3319 Melissa Weinberg, MD	Uridine (as Nucleomaxx supplement) or placebo for 8 weeks. Overnight GCRC visits required.	Stable ARV for >3 months Continuous d4T or AZT for >1 year HIV RNA <10,000 copies/mL for at least 30 days
COMPLICATIONS & CO-INFECTION STUDIES			
STUDY	CONTACT	DESIGN	BASIC CRITERIA
5232: Hepatitis A and B vaccination study	476-4082 ext 330 Deborah	Design 24 week study examining immune response to HAV and HBV vaccination	No ARV, CD4 >300, No previous OI's, No prior HAV/HBV vaccination, no evidence of HAV/HBV immunity (HCV and Hep B Core Antibody positive are eligible)
Acute HCV Study	476-4082 x556 Brad	24 weeks of treatment with Peg INF+RBV for pts w/rapid HCV clearance by week 8-12 or 24 weeks of RBV if no HCV clearance by 8 weeks	<ul style="list-style-type: none"> • HIV+ • Acute HCV (≤6months) • Detectable HCV RNA and: HCV ab- w/ detectable HCV RNA, or; HCV ab+ w/neg HCV antibody in past 6 months, or • ALT>5x ULN w/ normal levels in prior year and; current HCV ab+ and, last HCV ab was neg Excludes other causes of acute HCV
IGF1/IGF1 BP3 Effects of IGF-I / GFBP-3 in treatment of lipodystrophy.	206-4090 Viva	6 month study (6 months of treatment) GCRC visits required.	Stable ARVs > 2 months CD4>350 HIV RNA < 10,000
IMMUNOLOGIC STUDIES			
STUDY	CONTACT	DESIGN	BASIC CRITERIA
HIV EFFECTS ON IMMUNOLOGY: Effect of HIV on various immune system attributes	206-8103 Diane	1-time blood draw General health questionnaire Flexible time, location \$25 honorarium	HIV+ CD4<400 ARV treatment naïve No HCV infection No IV drug use

ARV=antiretroviral, HAART=highly active antiretroviral therapy, NRTI=Nucleoside reverse transcriptase inhibitor, NNRTI=non-nucleoside transcriptase inhibitor, PI=protease inhibitor, d4T=Zerit, 3TC=Epivir, ABC=Ziagen, ATV=Reyataz, EFV=Sustiva, FTC=Emtriva, LPV=Kaletra, Peg-IFN=pegylated interferon alfa 2a, RBV=ribavirin, RTV=Norvir, TDF=Viread BID=twice daily, GCRC=General Clinical Research Center, HCV=Hepatitis C, OBT=optimized background therapy, pt=patient, PMD=primary medical director, PK=Pharmacokinetic, RNA="viral load," subQ= subcutaneous injection



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UCSF Positive Health Program (PHP) OPEN ADULT HIV STUDIES – WINTER 2008

OBSERVATIONAL & OTHER STUDIES			
STUDY	CONTACT	DESIGN	BASIC CRITERIA
METRO: Observational study enrolling current methadone users	476-4082 x425 Jason Barbour	Urine screen, blood draw	HIV RNA > 1000 CD4 > 200
DAART: Directly Administered Antiretroviral Therapy in Methadone Maintenance	206-3993 Study Staff	12 months of tapered directly administered ARV therapy at methadone dispensary + medication adherence coaching	On methadone maintenance at SFGH-OTOP (Ward 93); on current ARV regimen for one month or longer
SCOPE: Observational study enrolling long-term non-progressors, elite suppressors, and viral controllers not taking ART	476-4082 Becky x139 Marcia x118	Questionnaire, blood draw, saliva collection every 2-4 months	Not taking ARVs HIV load consistently between: undetectable and 2000
STAYING WELL PROJECT: Effects of meditation-based stress management and education on physical health and well-being	353-9744 Patty or Susan	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
H.O.M.E.: Directly observed antidepressant therapy to improve depressive symptoms and HIV tx outcomes	514-9805 Scot or Sujana	Community-based DOT anti-depressant therapy vs. referral to AIDS Health Project.	Clinical depression English speaking HIV positive
M.D.O.T. Study: Improve ART adherence in the urban poor	476-0200 Michelle or Matt	Directly observed dosing of ART at Tenderloin field site vs. referral to standard of care.	HIV RNA > 400; Difficulty taking ART; Provider willing to or has prescribed ART; Live near Tenderloin; English speaking
POSITIVE QUIT: NIDA-funded study to evaluate smoking cessation treatment for HIV positive cigarette smokers	502-8437 Kevin Kelley	Randomly assigned into following: Self-help intervention Computer-based intervention Individual counseling (poss. eligible for Nicotine Patch or Gum)	HIV positive Current cigarette smoker Receiving primary care at Ward 86
STARTING/STOPPING THERAPY: Effects on CNS of HIV treatment initiation and interruption	206-4328 Evelyn	Interview, neurological testing, blood draw, spinal taps and/or MRI scans in longitudinal observational study	Patients starting or stopping antiretroviral therapy under guidance of primary provider
MINOCYCLINE: Effect of immunomodulating antibiotic treatment on CNS	206-4328 Evelyn	Open-label pilot study: minocycline for 8 weeks, then washout for 6 weeks. Spinal taps at 0, 4, 8 and 14 weeks	Subjects off of antiretroviral therapy
GENE TRANSFER STUDY: UCSF and ENZO Therapeutics are conducting a Phase I/II clinical trial looking at the effects of a Gene Transfer Treatment of Blood stem cells to fight HIV	353-2463 Sharon		HIV RNA > 400 and < 100,000 CD4 > 100 Resistance to 2 classes of ARVs or intolerance to 2 Regimens
ANAL HPV DISEASE AMONG HIV+AFRICAN AMERICAN MEN:	353-2463 Sharon		HIV+ African American male ≥ 18 yrs May or may not have anal warts
ANTIRETROVIRAL TREATMENT STUDIES			
STUDY	CONTACT	DESIGN	BASIC CRITERIA
A5221: Immediate vs. deferred ARV treatment for HIV pts treated for TB	514-0550 Michelle x354	Randomized, open-label study comparing ARV treatment (EFV/FTC/TDF) w/i 72hrs vs. treatment w/i 8-12 wks of starting TB treatment	Age ≥ 13 yrs HIV+ Treatment naïve TB regimen (RIF or RIF-based) CD4 ≤ 200 No documented MXDR TB

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