

UCSD Antiviral Research Center (AVRC)

Study List Spring 2011



619-543-8080

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Antiretroviral Studies – Treatment Naive

Study	Number	Design	Criteria
Comparison of NNRTI-sparing initial regimens	ACTG 5257	Open label. ATV/RTV + Truvada (TDF/FTC) vs. DRV/RTV + Truvada vs. RAL + Truvada.	Treatment naive. Female only. HIV RNA > 1000.

Antiretroviral Studies – Treatment Experienced

Study	Number	Design	Criteria
Effect of adding MVC to a suppressive ARV regimen with suboptimal CD4 recovery	CCTG 590	Open label. MVC added to current regimen.	Undetectable > one year. CD4 < 350. Currently receiving first ARV regimen.
GSK1349572 (integrase inhibitor) compared to Raltegravir in ARV experienced patients	ING111762 (Gilead)	GSK1349572 once daily vs. Raltegravir twice daily	HIV treatment experienced. Integrase inhibitor naive. Resistant to at least 2 ARV classes.
TXA 127 (Lymphocyte growth factor) added to a suppressive ARV regimen with suboptimal CD4 recovery.	Biotest TXA 127-2008-001	Open label, dose-escalating. Subcutaneous TXA 127 added to current regimen for 14 days.	HIV RNA < 50. CD4 < 250. Currently receiving HAART > 1 year.
OPTIONS Trial—Optimized treatment that includes or omits NRTIs for highly treatment experienced patients.	ACTG 5241	Selected regimens chosen from ENF, RAL, DRV/RTV, etravirine, TPV/RTV, plus two NRTIs or no NRTIs.	HIV RNA > 1000. Experience with 3 classes of ARVs. Currently taking a protease inhibitor. No experience with any integrase inhibitor, etravirine, or rilpivirine (TMC278).

Acute / Early Infection Studies

Study	Number	Design	Criteria
Standard of care (SOC) vs. SOC plus MVC in patients with acute HIV infection	Acute R-5	Randomized, placebo-controlled trial of ATV/RTV + Truvada (TDF/FTC) vs. ATV/RTV + Truvada + MVC.	Acute HIV infection.
Partner HIV transmission study (Partner Early Test)	AEH 027	Observational study of factors related to the transmission of HIV infection.	Partners of those taking The Early Test (nucleic acid testing).
Primary HIV infection study (First Choice Program).	AEH 020	Observational study of factors related to the acquisition of HIV infection.	Acute and early (< 3 months) HIV infection. Treatment naive.

Studies for Women

Study	Number	Design	Criteria
The HPV recombinant vaccine (Gardisal) in HIV positive women	ACTG 5257	All participants vaccinated at weeks 0, 8, and 24	Females, age 18–45 (HIV positive). No history of cervical cancer, no genital warts within 6 months, no prior HPV vaccinations. Either HIV RNA > 10,000 or CD4 < 350.

ART = antiretroviral therapy, ARV = antiretroviral, CSF = cerebrospinal fluid, HAART = highly active antiretroviral therapy, HCV = hepatitis C virus
 HPV = human papillomavirus, NRTI = nucleoside reverse transcriptase inhibitor, NNRTI = non nucleoside reverse transcriptase inhibitor,
 PI = protease inhibitor, TB = tuberculosis

ATV = atazanavir, DRV = darunavir, ENF = enfuvirtide, EFV = efavirenz, FTC = emtricitabine, LPV = lopinavir
 MVC = maraviroc, RAL = raltegravir, RBV = ribavirin, RTV = ritonavir, TDF = tenofovir, TPV = tipranavir

Complications and Co-infection Studies

Study	Number	Design	Criteria
HCV Entry Inhibitor (ITX 5061) in HCV mono-infected patients	ACTG 5277	Placebo controlled, dose escalation Phase 1b study of ITX 5061.	HCV mono-infected, genotype 1. HCV RNA > 100,000. No bridging fibrosis or cirrhosis. Liver biopsy required within 2 years.
GS-9451 and Tegobuvir with Peg2a + RBV in HCV mono-infected patients	GS-9190 (Gilead)	16 and 24 weeks of GS-9451, PEG2a + RBV with and without Tegobuvir. Then response guided PEG2a/RBV.	HCV mono-infected, genotype 1. HCV treatment naive.
PSI-7977 with PegIFN + RBV in HCV mono-infected patients	ATOMIC study (Pharmasset)	12 or 24 weeks of PSI-7977 with PEG/RBV. Arm C will be re-randomized to receive 12 weeks of PSI-7977 monotherapy or PSI-7977 with RBV.	HCV mono-infected, genotype 1, 4, 5, or 6. HCV treatment naive.
Evaluating the effect of Atorvastatin on biomarkers of inflammation, coagulopathy, angiogenesis and T-lymphocyte activation.	ACTG 5275	Continue current ARV regimen. Start Atorvastatin or placebo for 4–20 weeks, then switch to the other study arm.	Currently receiving PI-based regimen for at least 6 months. HIV RNA < 40. LDLc \geq 70 and < 130 mg/dL.
Pregabalin for the treatment of neuropathy	Pfizer A0081244	Pregabalin vs. placebo	HIV-associated neuropathy. No change in ARV regimen in the previous 8 weeks. Some medications are exclusions.
High dose vitamin D and calcium for patients initiating antiretroviral therapy	ACTG 5280	Vitamin D and calcium vs. placebo	HIV Treatment naive. HIV RNA > 1000. No current use of vitamin D, calcium, or steroids
Use of MRI to study fat in the abdomen and liver in patients with HIV-associated lipodystrophy	Contact Dr. Adrienne Schlang (619) 471-0509	60-minute MRI scan	HIV positive. Lipodystrophy (fat loss, fat deposits, other metabolic changes.)
Use of MRI to study fat in the abdomen and liver in ARV-naïve HIV positive patients		60-minute MRI scan	HIV positive. Treatment naive. No diabetes, Hepatitis B or Hepatitis C.

Other Studies

Study	Number	Design	Criteria
Zostavax (live herpes zoster vaccine) in HIV infected adults	ACTG A5247	Zostavax vs. placebo.	Undetectable HIV RNA. CD4 between 200 and 350. On stable ART.
Internet-based prevention intervention to reduce sexually transmitted infections in high risk HIV infected men who have sex with men.	CCTG 592	Internet risk-behavior survey, risk assessment and prevention messages vs. Internet risk-behavior survey alone.	HIV-infected men who have sex with men.
Treatment for the flu	IRC 003	Tamiflu, Amantadine + Ribarivin vs. Tamiflu only	Flu symptoms, other co-morbidities (like HIV). Must present within 72 hours of onset of symptoms.
Safety and Immunogenicity of Cytokine Enhanced HIV-1 Multi-Antigen pDNA Vaccine	ACTG 5281	Vaccine plus or minus IL12 vs. placebo. Injections at entry, week 4, and week 12.	On stable HAART > 6 months. CD4 > 500 and HIV RNA < 200 for 6 months. 18–55 years old.
Rifaximin as a modulator of gut microbial translocation and systematic immune activation in HIV infected individuals with incomplete CD4 recovery	ACTG 5286	Rifaximin vs. placebo for 4 weeks	On stable HAART > 96 weeks. CD4 < 350. Undetectable HIV RNA > 1 year.