

# UCSD Antiviral Research Center (AVRC)

## Study List Summer 2010



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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 naïve. 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
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 three classes of ARVs or resistance. 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 naïve.

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

More on other side.

## Complications and Coinfection Studies

Study	Number	Design	Criteria
Safety and efficacy of boceprevir in patients co-infected with HIV and HCV	Schering-Plough P05411	Step 1: Peginterferon 2B (Peg-IFN) plus RBV for 4 weeks. Step 2: then add boceprevir vs. placebo for 44 weeks.	Must be on ART for HIV. HIV RNA < 50. CD4 ≥ 200. HCV genotype 1, HCV treatment naïve. Liver biopsy required.
Pioglitazone prior to HCV treatment in those with insulin resistance and non-response to HCV therapy	ACTG A5239	Pioglitazone for 24-28 weeks, then add peginterferon 2A (Peg-IFN) + RBV. Open label, pilot study.	HIV/HCV coinfection (HCV genotype 1). CD4 > 200. Must have insulin resistance and non-response to previous therapy with Peg-IFN/RBV. Must be on stable or no antiretroviral therapy for 12 weeks.
Telaprevir (TVR) in combination with Peg-interferon Alfa-2a and Ribavirin (Peg-IFN/RBV) for the treatment of HIV/HCV co-infection.	VX08-950-110	Randomized, placebo-controlled Phase 2a study. 12 weeks on TVR/Peg-IFN/RBV, 12 weeks on Peg-IFN/RBV only. Peg-IFN/RBV for entire 48 weeks of study.	HIV/HCV co-infected (> 6 months). HCV genotype 1. Liver biopsy required. If ARV naïve: CD4>500; HIV RNA < 100,000. If ARV experienced: CD4 > 300; HIV RNA < 50. Current regimen must include Atripla or ATV/TDF (or 3TC).
Comparison of regimens among HIV-infected high-risk PPD TB skin test reactors who require treatment of latent infection to prevent TB	ACTG A5259	Weekly rifapentine + isoniazid for 3 months vs. daily Isoniazid for 9 months.	HIV-positive and HIV treatment naïve. No active TB and TB treatment naïve. PPD skin test reactors at high risk for developing TB.
Mefloquine for the treatment of progressive multifocal leukoencephalopathy (PML)	Biogen 111JC101	Mefloquine + local standard of care vs. local standard of care only. All participants will have the option of receiving mefloquine after 4 weeks.	Onset of PML symptoms within last 3 months.
Duloxetine and methadone for treatment of neuropathy	ACTG A5252	Placebo-controlled study with 4 weeks of duloxetine, 4 weeks of methadone, 4 weeks of both, and 4 weeks of neither, with the 4 week cycles in randomized order.	HIV-associated neuropathy. On current ARV regimen for at least 30 days or not planning to start ARVs.

## Studies for Women

Study	Number	Design	Criteria
The HPV recombinant vaccine (Gardasil) in HIV-positive women	ACTG A5240	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.
Comparison of NNRTI-sparing initial regimens	ACTG 5257	Open label. ATV/RTV + Truvada (TDF/FTC) vs. DRV/RTV + Truvada vs. RAL + Truvada.	Treatment naïve. HIV RNA > 1000.

## Other Studies

Study	Number	Design	Criteria
Chloroquine for reducing HIV-associated immune activation	ACTG A5258	Crossover design to evaluate the effect on CD8 T-cell activation of 12 weeks chloroquine vs. placebo.	HIV RNA > 20,000. CD4 > 400. Ages 18-65. Treatment naïve or off ART for 6 months, and unlikely to start ART for 6 months.
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.