

UC Davis AIDS Clinical Trials Unit

May, 2006

For information on any of these studies, call (916) 914-6322 or email actu@ucdavis.edu

* Studies Currently Enrolling *

Study	Description	Major Eligibility Criteria
Antiretroviral Naïve Studies		
A5164 Enrolling <i>Abby</i>	This is a randomized phase IV study of immediate vs. delayed antiretroviral therapy (ART) in subjects with advanced HIV disease who present with an acute AIDS-related opportunistic infection. Subjects must not have >30 days antiretroviral therapy in 6 months prior to study entry and none in the immediate 8 weeks prior to entry.	<ul style="list-style-type: none"> One of the following confirmed or probable OIs: PCP, bacterial pneumonia with CD4 <200, cryptococcal meningitis, disseminated histoplasmosis, disseminated MAC, CMV retinitis or encephalitis, toxoplasmic encephalitis, other invasive bacterial infection, or other atypical mycobacterial infection.
A5175 Enrolling <i>Tracy</i>	Phase IV, randomized open-label study comparing the effectiveness of 3 regimens: 1 containing 2 nucleoside reverse transcriptase inhibitors (NRTIs) + a protease inhibitor; and 2 regimens containing 2 NRTIs + a non-nucleoside reverse transcriptase inhibitor. Initial regimens are: Combivir + EFV; FTC + ATV + ddI; and FTC + TDF + EFV. All study meds but Combivir provided by study.	<ul style="list-style-type: none"> CD4 <300 cells/ mm³ within 90 days of entry. ≤ 7 days of prior antiretroviral therapy.
A5202 Enrolling <i>Abby</i>	A5202 is a large phase IIIB, randomized, open-label study comparing the effectiveness of 4 regimens: EFV + FTC/TDF + ABC/3TC placebo vs. EFV + ABC/3TC + FTC/TDF placebo vs. ATV/RTV + FTC/TDF + ABC/3TC placebo vs. ATV/RTV + ABC/3TC + FTC/TDF placebo.	<ul style="list-style-type: none"> HIV viral load >1000 copies/ml within 90 days of entry. ≤ 7 days of prior antiretroviral therapy. No evidence of any major resistance associated mutation on genotype.
Salvage Studies		
Achillion Enrolling <i>Melissa</i>	This is a randomized, double-blind study of Elvucitabine versus Lamivudine administered once daily in conjunction with background ART, to HIV-1 infected subjects with documented M184V variant.	<ul style="list-style-type: none"> HIV viral load >5000 and <150,000; CD4 count >100 cells/ mm³ Must have documented M184 variant Stable ART regimen that contains lamivudine or emtricitabine Hepatitis B surface antigen negative.
Immunology Studies		
A5176 Enrolling <i>Tracy</i>	A5176 is a 61 week, phase I/II randomized, trial designed to evaluate the safety, tolerability, and immunogenicity of a candidate topical therapeutic DNA vaccine, DermaVir, for the treatment of individuals with HIV-1 infection who are virologically suppressed with HAART.	<ul style="list-style-type: none"> CD4 count >350 cells/ mm³ and nadir (lowest) CD4 >250 cells/ mm³ HIV viral load < 50 copies/ml on stable ART regimen for at least 12 weeks prior to study entry.
A5192 Enrolling <i>Melissa</i>	A5192 is an 18 week, phase II, open-label pilot study designed to explore the antiretroviral activity, safety, and tolerability of pegylated interferon (PEGASYS®) in antiretroviral experienced subjects who are currently off HIV meds.	<ul style="list-style-type: none"> CD4 count ≥ 300 cells/ mm³ and HIV viral load ≥ 5000 copies/ml Hepatitis B surface antigen and Hepatitis C antibody negative Must have had ART in the past but be off all ARTs for 12 weeks prior to study entry and willing to delay restart for duration of study (18 weeks).
A5197 Enrolling <i>Abby</i>	A5197 is a phase II, randomized, placebo controlled trial designed to determine if the immune responses elicited by the MRK Ad5 HIV-1 Gag vaccine are capable of lowering HIVRNA levels following interruption of antiretroviral therapy for 16 weeks. Subjects must have well documented viral suppression for last 2 years.	<ul style="list-style-type: none"> CD4 ≥ 500 cells/mm³ and HIV viral load <50 at screening 40 subjects will be allowed to enroll with confirmed nadir CD4 of 200-300 prior to starting ART. After that, nadir CD4 cannot be < 300. Subjects must be on stable ART for 4 weeks prior to entry. Hepatitis B surface antigen negative.
A5214 Enrolling <i>Tracy</i>	A5214 is an 8 week phase I, randomized, placebo controlled, dose escalation study evaluating the safety of subcutaneous single dose Interleukin-7 (IL-7) in HIV+ individuals.	<ul style="list-style-type: none"> CD4 count ≥ 100 cells/ mm³ and HIV viral load ≤50,000 copies/ml. On HAART for at least 12 months without any change in last 3 months. No AIDS defining diagnoses in last 12 months & no prior interleukins. Hepatitis B surface antigen and Hepatitis C antibody negative.

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Other		
A5184 Enrolling <i>Tracy</i>	A5184 is an HCV/HIV coinfection, open-label study designed to determine the impact of antiretroviral treatment on the efficacy of hepatitis C treatment with pegylated interferon alfa-2a and ribavirin (PEG/RBV) in HCV/HIV-coinfected subjects. Subjects will be randomized to receive ART in addition to PEG/RBV treatment or to receive PEG/RBV treatment alone.	<ul style="list-style-type: none"> • CD4 count \geq 300 cells/ mm³ and HIV viral load >1000 copies/ml. • Must be willing to accept randomization to either initiating the protocol-specified ART regimen or postponing HIV therapy • Must not have received more than 31 days cumulative therapy at any time of either: 3TC, TDF, PI, or NNRTI • Hepatitis B surface antigen negative
Pfizer-Pregabalin Enrolling <i>Monica</i>	This is a 15 week randomized, double-blind, placebo-controlled trial to compare the efficacy, safety & tolerability of pregabalin vs. placebo in the treatment of neuropathic pain associated with HIV neuropathy.	<ul style="list-style-type: none"> • Must have neuropathic pain associated with HIV distal sensory polyneuropathy for \geq 3 months. • No neurologic disorders unrelated to HIV. • Stable analgesic regimen for at least 1 month. • Stable use or non-use of DDI, DDC, or D4T
Mucosal Enrolling <i>Bryce/ Melissa</i>	This is an NIH sponsored, observational study designed to advance understanding of T cell responses to HIV in mucosal surfaces (cervical, and rectal). The mucosal tissue immune response will be compared to that documented in blood samples. All subjects undergo flexible sigmoidoscopy.	<ul style="list-style-type: none"> • HIV+ males and females and seronegative controls. • CD4 \geq 200 cells/ mm³ and HIV viral load \geq 5000 copies/ml • Off antiretroviral therapy or interrupting therapy.
A5001 Open	Adult Longitudinal Linked Randomized Trials (ALLRT) Protocol. This is a long-term observational study.	<ul style="list-style-type: none"> • HIV-infected subjects who are enrolled in other AACTG treatment protocols and agree to be followed long-term for clinical, virologic, immunologic, and pharmacologic endpoints.

Pending Studies

Hepatitis / Co-infection Studies

HBV Pending <i>Nancy</i>	An 18 month study measuring immune response to Hepatitis B vaccination in minorities, both HIV infected and HIV negative controls. Subjects receive a standard vaccination series from their provider. Blood specimens will be analyzed to measure cellular response.	<ul style="list-style-type: none"> • Age 18-50 years old • Hepatitis B negative • If HIV+, must be on ART with CD4 \geq350 cells/ mm³ and HIV viral load <10,000 copies/ml
Other		
A5229 Pending <i>Abby</i>	A5229 is a phase II/III, randomized, double-blind, placebo-controlled study of uridine supplementation in the form of NucleomaxX [®] for the treatment of HIV-associated lipodystrophy.	<ul style="list-style-type: none"> • Must be on stable ART regimen containing ZDV or d4T • HIV viral load \leq 5000 copies/ml • Clinical lipodystrophy in at least two areas: face, arms, legs, or buttocks