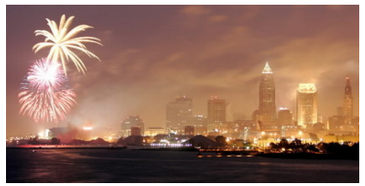
Case/UH AIDS Clinical Trials Unit



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For more information on Case/UH clinical trials please contact Kristen Allen, RN at (216) 844-8136 or allen.kristen@clevelandactu.org

	What It Does	How It Does It	Who Can Participate
		Inflammation	
AIDS 347	Placebo-controlled crossover study to determine if the provision of tocilizumab (TCZ) is safe and well tolerated and whether it lowers inflammation. Trial lasts 46 weeks with 13 scheduled visits. Compensation and mileage reimbursement provided.	Half of participants receive 1 dose of TCZ every four weeks for the 1st two months (total of 3 doses) and half will get placebo. Crossover at month 5 with prior placebo recipients receiving TCZ.	HIV+ people, 18-60 yrs old. Viral load < 200 for at least 96 weeks (one VL <1,000 allowed). CD4+ 350 – 1,000 and VL<50 at enrollment. Must be on same ART regimen for ≥24 weeks; however, if changed for non-virologic failure reasons, change permissible >8 weeks before enroll. Regimen must not contain maraviroc. No hep B or C coinfection.
A5332 REPRIEVE	72-month, placebo-controlled phase IV study to determine effect of pitavastatin as primary preventive therapy on CVD events. Enrolling people on ART not meeting 2013 ACC/AHA guidelines for statin recommendation. Compensation and mileage reimbursement provided.	Two arm trial. 1:1 randomization. Arm A: pitavastatin 4mg daily Arm B: Placebo daily. Women of reproductive capacity must agree to use approved forms of contraception.	HIV+people, ages 40 ≥ and ≤ 75. On ART ≥6 mos. CD4+ >100. No clinical ASCVD, as defined by 2013 ACC/AHA guidelines, including a previous diagnosis of any of the following: AMI; acute coronary syndromes; stable or unstable angina; coronary or other arterial revascularization; stroke; TIA; peripheral arterial disease presumed to be of atherosclerotic origin. Cancer free >3 yrs. No known cirrhosis. No untreated symptomatic thyroid disease.
5336	12 week, randomized, open-label trial of ruxolitinib to determine safety/tolerability and changes in systemic immune activation and inflammation. Compensation provided.	Participants take study drug for 5 weeks. 2:1 randomization to Arm A: Ruxolitinib 10mg orally BID + participant's ART regimen Arm B: ART regimen (no study drug). ART regimen not provided by study.	HIV+ adults 18–75 years old; CD4 >350. On continuous ART >2 yrs with documented viral suppression >2 yrs. (One blip ≤200 allowed in 2nd yr before entry). No changes in ART <12 wks prior to entry. ART must contain either TDF/FTC or ABC/3TC plus NNRTI or INSTI, not containing cobicistat (no Stribild). No history of PML.
5350	38 week, randomized, double-blind, placebo controlled trial of probiotic Visbiome Extra Strength (Visbiome ES) to determine safety/tolerability as well as changes in sCD14. Compensation provided.	1:1 randomization to one of two arms: Arm A: 2 wk lead-in period: 1 Visbiome sachet per day; then increase to 1 sachet twice per day for 22 weeks. Followed by 12 weeks off treatment. Arm B: Identical regimen as Arm A, but with placebo sachets.	HIV+ adults on continuous ART for at least 48 weeks, with no interruptions >7 continuous days. No plans to change ART regimen during the trial. Undetectable VL for ≥48 weeks. CD4 ≥ 200. No chronic hepatitis B or C.

	What It Does	How It Does It	Who Can Participate
	Neurocognition		
5324 HAND	**OPEN** 96-week, placebo-controlled clinical trial to determine if adding maraviroc and/or dolutegravir reduces HIV-associated neurocognitive disorder (HAND). Compensation provided.	Participants will be randomized to one of three arms Arm A: placebo for maraviroc and placebo for dolutegravir Arm B: dolutegravir and placebo for maraviroc Arm C: maraviroc and dolutegravir	HIV+ adults ≥ 18 years. On current ART ≥ 12 months. HIV VL <50. No more than one VL 50–200 within the last 6 months. At least mild HAND based on testing done at screening. No medical condition not related to HIV that may cause cognitive impairment. No current hepatitis C. No prior/current use of integrase inhibitor or maraviroc.
	Hepatitis C Coinfection		
5329	Non-randomized, open label, phase II study of IFN-free Hep-C therapy for either 24 or 12 weeks in co-infected people. Prelim data from phase III in mono-infected Hep C of same study drugs yielded SVR rates of ≥ 92%. Study drugs: HCV DAA of ABT-450/ABT-267 plus ABT-333 and RBV. Compensation provided.	ABT-450/r/ABT-267 (150/100/2f mg) by mouth once a day plus ABT-333 (250mg) by mouth twice a day plus Ribavirin 1000–1200mg (based on wt) divided into 2 doses (twice a day). Subjects will be treated for either 12 or 24 wks, but neither subject nor provider will be able to choose duration of treatment. All subjects followed for 48 weeks on study.	HIV+ adults, 18-70 yrs old; HIV VL <50. No history of HIV virologic failure; no HIV genotypic resistance to any ARV. CD4 ≥ 200; CD4 cell % ≥14%. BMI: ≥18 to ≤38 kg/m2. Must be on specific HIV ARV reg for at least 8 wks: a. Tenofovir plus emtricitabine q.d. (or fixed-dose Truvada) **or** tenofovir plus lamivudine q.d. (or fixed-dose TDF/3TC), plus b. raltegravir 400 mg b.i.d. **or** darunavir 800mg q.d. with ritonovir 100mg q.d. HCV VL >10,000, HCV genotype 1. HCV treatment naïve (very few exceptions). No history of decompensated liver disease; no active depression/uncontrolled mental health disorders. Not pregnant/breastfeeding or have partner who is pregnant.
	Trials for HIV-Negative People		
HVTN 704 AMP Study	Randomized, placebo-controlled phase IIB trial evaluating safety and efficacy of a broadly neutralizing monoclonal antibody (VRC01) in reducing acquisition of HIV-1 infection. Compensation provided.	Each participant will be in the trial for 21 months; clinic visits approximately monthly. At 10 visits (every other month), participants will receive VRC01/placebo through infusion. Ongoing HIV risk-reduction counseling provided. Participants have option to obtain PrEP drugs through trial at no cost.	HIV-negative MSM (transgender men inclusive) and transgender women who have sex with men, ages 18-50. Good general health. BMI <40. No asthma, other than mild, well-controlled asthma. Sexual history taken at screening visit.

Our physicians welcome calls/emails from other HIV-treating physicians who would like to discuss a clinical issue with them

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