AIDS Clinical Trials Unit

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ACTU Website:
www.uphs.upenn.edu/pennactu

Patient Benefits - All studies provide $20 per visit, some have additional compensation.

Physician Benefits - All lab work can be faxed, mailed or emailed. An updated lab flow sheet is also sent .

The AIDS Clinical Trials Unit

Update of HIV/AIDS Investigational Therapies

Following is a list of studies . A complete list of all studies enrolling at our ACTU can be found on our website at: www.uphs.upenn.edu/pennactu

Click on the topic below to view related category.

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Patients not on Treatment

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ACTG A5296 Sevelamer: Sevelamer Carbonate for Reducing Endotoxemia and Immune Activation: A Proof of Concept

Criteria: No plans to start ART. CD4 count ≥ 400 with detectable viral load.

Treament: Subjects will receive 8 weeks of treatment with sevelamer, 1,600 mg orally three times a day with an additional 8 weeks of observation.

Drug(s) Provided by the Study: Sevelamer **Compensation:** $

Emend 3: A Phase IB, Randomized, Placebo Controlled, Double Blind Study to Determine the Safety, Viral Suppressive Potential, Pharmacokinetics and Immune Modulatory Effects of Treatment With Aprepitant (Emend) in HIV Infected Individuals

Criteria: No plans to start ART. CD4+ cell count ≥ 350/mm^3 ,Plasma HIV-1 RNA of ≥2,000 copies/mL, No Chronic Hep B or C

Treatment:

Arm A: Aprepitant Placebo

Arm B: Aprepitant 375 mg QD

Drug(s) Provided by the Study: Aprepitant (Emend) or matching placebo **Compensation:** $$

Observational Studies

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Pfizer A4001067 POEM: An International, Multicenter, Prospective Observational Study of the Safety of Maraviroc Used with Optimized Background Therapy in Treatment-Experienced HIV-1 Infected Patients

Purpose: The purpose of the study is to estimated the incidence rates of Category C OI's, viral encephalitis, liver failure and rhabdomolysis in treatment-experienced HIV-1 infected patients receiving maraviroc during time of use and for up to six months following the discontinuation of treatment,

Drug(s) Provided by the Study: None - A Tropism assay will be performed if needed **Compensation:** $$

NOTE: Study is open to anyone needing a Tropism. Patient can go onto study if they receive Maraviroc or not.

Antiretroviral Naïve - (Never Treated Before)

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Tobira-652, Cenicriviroc: A Phase 2b Randomized, Double-Blind, Double-Dummy Trial of 100 or 200 mg Once-Daily Doses of Cenicriviroc (CVC, TBR-652) or Once-Daily EFV, Each with Open-Label FTC/TDF

Criteria: Viral Load ≥ 5,000, CD4 ≥ 250, nadir of 200; CCR5 tropic and sensitive to EFV, TDF and FTC. No active Hep B or C

Purpose: To determine Efficacy, Safety and Tolerability of two-dose levels of Cenicrivroc vs. Efavirenz, each with open-label FTC/TDF

Treatment:
100 or 200 mgs of Cencriviroc or Efavirenz with FTC/TDF. Placebo-controlled. CVC is 50 mg tablets.

Drug(s) Provided by the Study: All study meds are provided. **Compensation:** $$$

ACTG-A5303, Maraviroc Study: A Phase 2b, Double-Blind, Placebo-Controlled, Exploratory Randomized Trial to Determine the Bone, Immunologic, Virologic, and Neurocognitive Effects of a Novel Maraviroc-Containing Antiretroviral Regimen in Treatment-Naïve Patients Infected with R5-Tropic HIV-1

Criteria: Viral Load ≥ 1,000, CCR5 Tropic

Purpose: To compare the effects of: DRV/r 800/100 mg + MVC 150 mg + FTC 200 mg QD versus DRV/r 800/100 mg + TDF 300 mg + FTC 200 mg QD on bone mineral density (BMD) as measured by the change in total hip BMD from baseline to week 48 of treatment.

Treatment:

ARM A: Darunavir 800 mg PO QD + Ritonavir 100 mg PO QD + Maraviroc 150 mg PO QD + Emtricitabine 200 mg PO QD + Placebo for Tenofovir PO QD

ARM B: Darunavir 800 mg PO QD + Ritonavir 100 mg PO QD + Emtricitabine 200 mg PO QD + Tenofovir 300 mg PO QD + Placebo for Maraviroc PO QD

Drug(s) Provided by the Study: All Study Meds are provided. **Compensation:** $

Pending **ACTG-A5292, Statin-Atripla:** A Randomized Controlled Trial to Examine and Compare the Effects of HAART versus Statin Therapy on Endothelial Function and Markers of Inflammation/Coagulation in HIV-Infected Individuals with High CD4 Counts

Criteria: CD4 ≥500, No use of a lipid lowering medication within the past 60 days, No resistance to components of Atripla

Purpose: To compare the effects of a) statin therapy alone, b) potent ART alone and c) potent ART combined with statin therapy on change in cardiovascular risk over 8 weeks in HIV-infected patients with CD4 cell counts greater than 500.

Treatment:

Arm A: Pravastatin 40mg once daily for 24 weeks.

Arm B: Atripla 1 Tablet once daily for 12 weeks, then adding Pravastatin 80mg once daily for an additional 12 weeks while continuing the Atripla for 12 weeks.

Arm C: Pravastatin 80mg daily plus Atripla once daily for 24 weeks.

Drug(s) Provided by the Study: All Study Meds are provided. **Compensation:** $

Pending **GSK- ING114915 Flamingo Study**: A Phase IIIb, randomized, open-label study of the safety and efficacy of GSK1349572 (dolutegravir, DTG) 50 mg once daily compared to darunavir/ritonavir (DRV/r) 800 mg/100 mg once daily each administered with fixed-dose dual nucleoside reverse transcriptase inhibitor therapy over 96 weeks in HIV-1 infected antiretroviral naïve adult subjects.

Criteria: Viral Load ≥ 1,000.

Purpose: To demonstrate the non-inferior antiviral activity of DTG 50 mg administered once daily compared to DRV/r 800 mg/100 mg once daily with fixed-dose NRTI background over 96 weeks in HIV-1 infected therapy naïve subjects.

Treatment:

Arm A: Dolutegravir once daily: 1 x 50mg DTG tablet and 1 x fixed dose dual NRTI tablet (ABC/3TC orTDF/FTC).

Arm, B: Darunavir once daily: DRV (2 x 400 mg tablets), RTV (1 x 100 mg tablet) and 1 x fixed dose dual NRTI tablet (ABC/3TC or TDF/FTC) with food.

Drug(s) Provided by the Study: All study meds are provided. **Compensation:** $$$

Patients with Well-controlled Virus

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GS-US-236-0115: Randomized, open-label, multicenter, active-controlled study to evaluate switching from regimens consisting of a ritonavir-boosted protease inhibitor plus FTC/TDF to the single tablet regimen, Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate (EVG/COBI/FTC/TDF) in virologically-suppressed, HIV-1 infected subjects.

Criteria: Currently on ritonavir-boosted PI (1st or 2nd regimen). Viral Load undetectable. No integrase inhibitor experience.

Treament:

Arm 1: Switch to single tablet regiment (STR) consisting of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/COBI/FTC/TDF)

Arm 2: Remain on current antiretroviral regimen consisting of a ritonavir boosted protease inhibitor plus FTC/TDF for 48 weeks after baseline.

Drug(s) Provided by the Study: ARM 1: EVG/COBI/FTC/TDF
ARM 2: Truvada

Compensation: $$

ACTG A5275 , Atorvastatin: A Pilot Study Evaluating the Effect of Atorvastatin on Biomarkers of Inflammation, Coagulopathy, Angiogenesis, and T-lymphocyte Activation in HIV-1 Infected Individuals with Suppressed HIV-1 RNA and LDL Cholesterol < 130 mg/dL

Criteria: Currently on boosted PI regimen with viral load undetectable and normal lipids. No history of CAD or diabetes, No chronic Hep B or C

Treatment:

Arm A: At study entry, continue ARV regimen and start atorvastatin 10 mg with crossover to placebo at week 24. Dose escalation at week 4.

Arm B: At study entry, continue ARV regimen and start atorvastatin placebo with crossover at week 24. Plabcebo dose escalation at week 4.

Drug(s) Provided by the Study: atorvastatin

Compensation: $$

ACTG A5258, Chloroquine: Phase II Study of Chloroquine for Reducing HIV-associated Immune Activation

Criteria: CD4+ cell count < 350 cells/mm^3, HIV-1 RNA undetectable, Taking ART for at least 24 months prior to study entry, and not likely to change regimen within the next 6 months.

Treament:

Arm 1: 12 weeks of chloroquine followed by 12 weeks of placebo

Arm 2: 12 weeks of placebo followed by 12 weeks of chloroquine.

Drug(s) Provided by the Study: chloroquine or matching placebo

Compensation: $

Statin Study: Statin modulation of monocyte activation: a pilot study for potential use in NeuroAIDS

Criteria: HIV-1 RNA undetectable, CD4 > 350, not on lipid-lowering agents, not on anti-inflammatory drugs

Treament: Atorvastatin for 12 weeks

Drug(s) Provided by the Study: atorvastatin

Compensation: $$

Experimental Therapeutics

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Adaptimmune: A Pilot, Open Label, Multiple Arm, Single Center Study to Evaluate the Safety and Tolerability of Escalating Doses of Autologous T Cells Modified with Lentiviral Expressing a High Affinity Gag-Specific TCRS in HLA-A*02 Patients with HIV

Purpose: To determine optimal dose and to evaluate the safety and tolerability of the modified Autologous T Cells.

Main Requirements: HIV infection, ≥ 18 years with undetectable HIV-1 RNA levels and CD4+ T Cell counts ≥ 450.

Drug(s) Provided by the Study: Autologous CD8 T Cells transduced with a lentiviral vector

Compensation: $$

Salvage - Resistant to Current Therapy

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GSK- 112574, VIKING Study: A Phase III study to demonstrate the antiviral activity and safety of dolutegravir in HIV-1-infected adult subjects with treatment failure on an integrase inhibitor containing regimen.

Criteria: VL ≥ 500, on stable ART failing Raltegravir or Elvitgravir. No Tipranavir or fosamprenavir in current regimen. NNRTIs are stopped 14 days prior to entry.

Purpose: To assess safety, tolerability and the antiviral activity of DTG 50mg twice daily (BID) administered failing background therapy to Day 8 and thereafter with optimized background ART (OBR) consisting of at least one fully active agent through Week 24 in HIV-infected
adult subjects with virological failure on a prior INI containing regimen.

Treatment: Dolutegravir, 50mg twice daily administered initially with the current failing regimen but with an optimized background regimen after Day 7 chosen by the Investigator and Primary Care Provider.

Drug(s) Provided by the Study: Only Dolutegravir is provided by the study. **Compensation: $$$**

BMS A1438011, Attachment Inhibitor Study: A Phase IIb Randomized, Controlled, Partially-Blinded Trial to Investigate Safety, Efficacy and Dose-response of BMS-663068 in Treatment-experienced HIV-1 Subjects, Followed by an Open-label Period on the Recommended Dose.

Criteria: VL ≥ 1,000, CD4 > 50. Susceptibility to ATV, RAL and TDF. No Hep C, Positive Hep BsAg exclusionary

Purpose: To assess the safety and efficacy of four doses of BMS-663068 by determining the proportion of subjects with plasma HIV-1 RNA < 50 c/mL at Week 24.

Treatment:
Subjects randomized to one of the AI Treatment Groups will receive: AI dose of BMS-663068 (either 400 mg BID, 800 mg BID, 600 mg QD, or 1200 mg QD) + raltegravir 400 mg BID + tenofovir 300 mgQD; all oral administration with food for at least 96 weeks.

Subjects randomized to the Reference Treatment Group will receive: ATV/r 300/100mg QD + raltegravir400 mg BID + tenofovir 300 mg QD; all oral administration with food for at least 96 weeks.

Drug(s) Provided by the Study: All study meds are provided. **Compensation: $$**

Phone Numbers:

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Ask for a Study Nurse to help you.

Published by: Thomas Kenney