Jorge L. Santana, MD
Director e Investigador Principal Proyecto ACTU
IUPR-CTU

Proyecto ACTU

Rev. por: SID, 13/MAR/2019

ESTUDIOS ABIERTOS A RECLUTAMIENTO	Criterios Inclusión Generales
A5345: Identification of Biomarkers to Predict Time to Plasma HIV RNA Rebound and Post-Treatment Viral Control during an Intensively Monitored Antiretroviral Pause (IMAP). **Sub-estudio A5347s** ONLY Cohort B	➢ Diagnóstico VIH+ ➢ entre 18 y 70 años de edad. ➢ Conteo de CD4+ ≥200 cells/uL ➢ Carga Viral de VIH <20 copias/mL (Roche TaqMan v2.0) o <40 copias/mL (Abott).
A5369: HIV-1-Gag Conserved-Element DNA Vaccine (p24CE) as Therapeutic Vaccination in HIV-Infected Persons with Viral Suppression on Antiretroviral Therapy	➢ Diagnóstico VIH+ ➢ entre 18 y 65 años de edad. ➢ Conteo de CD4+ >500 cells/uL ➢ Carga Viral de VIH indetectable ➢ Estable en ART por los pasados 2 años
Próximos a Comenzar Reclutamiento:	
A5359: Long-Acting Antiretroviral Therapy in Non-adherent HIV-Infected Individuals	➢ Diagnóstico VIH+, ≥18 años de edad ➢ Poco adherencia a la terapia ART ➢ Carga Viral de VIH >200 copias/mL
En proceso permiso de IRB	
A5357: A Proof-of-Concept Study of Long-Acting Cabotegravir Plus VRC01LS to Maintain Viral Suppression in HIV-1-infected Adults.	➢ Diagnóstico VIH+, ≥18 años de edad. ➢ Conteo de CD4+ ≥350 cells/uL ➢ Carga Viral de VIH <50 copias/mL entre los pasados 2 años
A5370: Safety, Pharmacokinetics and Immunotherapeutic Activity of an Anti-PD-1 Antibody (REGN2810) in HIV-1-infected Participants on Suppressive cART: A Phase II, Double-blind, Placebo-controlled, Ascending Multiple Dose Study	➢ Diagnóstico VIH+ ➢ entre 18 y 65 años de edad. ➢ Peso ≥ 110 libras ➢ Conteo de CD4+ ≥350 cells/uL ➢ Carga Viral de VIH indetectable
A5375: An Open-Label, Phase II Pharmacokinetic Study to Evaluate Double-Dose Levonorgestrel Emergency Contraception in Combination with Efavirenz-Based Antiretroviral Therapy or Rifampicin-Containing Anti-Tuberculosis Therapy	➢ Diagnóstico VIH+ ➢ Mujeres entre ≥18 años de edad. ➢ Terapia ART estable que incluya una vez al día DTG 50 mg o EFV 600 mg
A5377: A Phase I, First-in-human, Ascending Dose Study of SAR441236, a Tri-specific Broadly Neutralizing Antibody in HIV-infected Participants.	➢ Diagnóstico VIH+, entre 18 y 70 años de edad. ➢ **RAMA A:** Conteo de CD4+ ≥200 cells/uL, carga Viral de VIH <50 copias/mL y estar en ART por los pasados 12 meses. ➢ **RAMA B**: ≥350 cells/uL y Carga Viral de VIH >500 y <100,000 copias/mL, No estar en ART ➢

Para más información: Daniel Casiano, Director Equipo de Comunidad
◆ daniel.casiano@upr.edu ◆ Tel. 787-767-9192, -9193, -9194, -9195 ◆ Fax 787-754-8002
P.O. Box 365067 San Juan, PR 00936-5067

Jorge L. Santana, MD
Director e Investigador Principal Proyecto ACTU
IUPR-CTU

Futuros Estudios:

A5355: Phase I, Double-Blind, Randomized, Placebo-Controlled Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Modified Vaccinia Ankara (MVA)-based anti-CMV Vaccine (Triplex®), in Human Immunodeficiency Virus (HIV)-1 and CMV Co-Infected Adults who are on Potent Combination ART with Conserved Immune Function

A5363: A Multicenter, Prospective, Double-Blind, Randomized Placebo-Controlled Study to Evaluate the Effects of Cenicriviroc on Arterial Inflammation in People Living with HIV.

A5364: A Phase 1, Randomized, Open-Label, Study of the Safety, Pharmacokinetics and Ability to Durably Prevent Viral Relapse During a Monitored Analytical Treatment Interruption of a Combination of the Broadly Neutralizing Antibodies 3BNC117-LS and 10-1074-LS

A5368: "Safety, Pharmacokinetics and Immunotherapeutic Activity of an Anti-PD-1 Antibody in HBV Infected Participants on Suppressive Antiviral Therapy: A Phase I/II Ascending Multiple Dose Study"

A5376: Pharmacokinetic Interactions of Etonogestrel Subdermal Implants (ENG) with Rilpivirine (RPV) Combined with Tenofovir Alafenamide (TAF) and Emtricitabine (FTC)
A5379: HBV Vaccination in HIV-Infected Persons: Randomized,Controlled Trials of HEPLISAV-B vs. Engerix-B.

A5380: Glecaprevir/pibrentasvir Fixed-dose CombinationTreatment for Acute Hepatitis C Virus Infection (PURGE-C)

A5382: A Phase II Randomized Study Assessing the Safety and Efficacy of 24 Weeks of REP 2139-Mg, Followed by 48 Weeks of Combined Therapy with REP 2139-Mg and Pegylated Interferon Alpha-2a in Participants with HBeAg Negative Chronic HBV Infection Suppressed with Nucleos(t)ides

A5383: Randomized, Placebo-Controlled Trial to Evaluate the Safety of Letermovir (Prevymis) in Human Immunodeficiency Virus (HIV)-1 & CMV Co-Infected Adults who are on Suppressive ART & its Effect on Chronic Inflammation, HIV Persistence & Other Clinical Outcomes

Para más información: Daniel Casiano, Director Equipo de Comunidad
◆ daniel.casiano@upr.edu ◆ Tel. 787-767-9192, -9193, -9194, -9195 ◆ Fax 787-754-8002
P.O. Box 365067 San Juan, PR 00936-5067