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Proyecto ACTU

Rev. por: SID, 27MAR2020

ESTUDIOS ABIERTOS A RECLUTAMIENTO Enrollment into all open studies will halt until further notice.	Criterios Inclusión Generales
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
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
A5380: Glecaprevir/pibrentasvir Fixed-dose CombinationTreatment for Acute Hepatitis C Virus Infection (PURGE-C)	➢ ≥18 años de edad. ➢ VHC co-infectado con VIH ➢ o VHC mono infectado
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
Próximos a Comenzar Reclutamiento: No NEW ACTG study will open to accrual until further notice.	
U54 Trial #1: Nine-valent HPV Vaccine to Prevent Persistent Oral HPV Infection in Men living with HIV	➢ Diagnóstico VIH+ ➢ Hombre/Mujer trans ➢ entre 20 y 50 años de edad
GS-US-200-4334: A Phase 2 Randomized, Open Label, Active Controlled Study Evaluating the Safety and Efficacy of Long-acting Capsid Inhibitor GS-6207 in Combination with Other Antiretroviral Agents in People Living with HIV	➢ Diagnóstico VIH+ ➢ ≥18 años de edad ➢ No haber usado ATR
AbbVie M19-939: A Randomized, Double-blind, Placebo-controlled, Phase 1b Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of ABBV-181 in HIV-1 Infected Adults.	➢ Diagnóstico VIH+ ➢ Entre 18 y 65 años de edad ➢ Conteo de CD4+ ≥500 cells/uL
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
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"	➢ entre 18 y 70 años de edad. ➢ Mono Infección VHB
A5379: HBV Vaccination in HIV-Infected Persons: Randomized,Controlled Trials of HEPLISAV-B vs. Engerix-B. ADVARRA	➢ Diagnóstico VIH+, Entre ≥18 y ≤70 años de edad, Conteo de CD4+ ≥100 cells/uL y HIV-1 RNA <1000
A5386: IL-15 Superagonist (N-803) with and without Combination Broadly Neutralizing Antibodies ADVARRA	➢ Diagnóstico VIH+, Entre ≥18 y ≤65 años de edad, ➢ Conteo de CD4+ >450 cells/uL ➢ HIV-1 RNA <50

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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

A5376: Pharmacokinetic Interactions of Etonogestrel Subdermal Implants (ENG) with Rilpivirine (RPV) Combined with Tenofovir Alafenamide (TAF) and Emtricitabine (FTC)

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

A5387: Two bNAbs (PGT121.BIJ414.LS and VRC07-523LS) in Combination with TLR9 agonist (Lefitolimod)

A5388: Combination HIV-Specific Broadly-Neutralizing Monoclonal Antibodies Combined with ART Initiation.

A5389: A Phase I Study to Evaluate the Safety and Antiviral Activity of Two Human Monoclonal Antibodies (VRC07-523LS and PGT121LS) Administered to HIV Infected Participants Who Initiated ART During Acute or Chronic HIV-1 Infection

A5391: Effect of a Switch to Doravirine Among Persons with Excessive Weight Gain on Integrase Inhibitors and Tenofovir Alafenamide Fumarate.

A5392: Pharmacokinetic Interactions of Etonogestrel (ENG) Subdermal Implants with Long-Acting Rilpivirine (RPV-LA) and Cabotegravir (CAB-LA) in Participants of Reproductive Potential.

A5395: A Randomized, Controlled, Open-Label, Trial to Evaluate the Efficacy of Hydroxychloroquine (HCQ) and Azithromycin versus Vitamin C to Prevent Hospitalization and Death in Persons with COVID-19

https://md.rcm.upr.edu/actu5401/

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