



CORNELL CLINICAL TRIALS UNIT

Unlocking the mysteries of HIV Treatment

HIV TREATMENT STUDIES

START (STRATEGIC TIMING OF ANTIRETROVIRAL TREATMENT)

- HIV+ men and women age ≥ 18 years
- CD4+ cell count ≥ 500 cells/mm³
- Antiretroviral naive

The START study is not testing investigational antiretrovirals. This study compares the risks and benefits of starting ART at CD4+ cell counts over 500/mm³ compared to waiting until CD4+ cell counts drop to 350/mm³. The choice of ART is up to the primary provider. Nearly all ART is available free of charge through the study.

Study Regimen:

EARLY Group: will start ART immediately

DEFERRED Group: will NOT take HIV medicines while in the study until CD4+ cell count drops to 350/mm³. At that time, the healthcare provider will choose HIV medicines that the subject will begin to take.

A5280: HIGH-DOSE VITAMIN D AND CALCIUM FOR BONE HEALTH IN HIV+ INDIVIDUALS STARTING ANTI-HIV MEDICATIONS

- HIV+ men and women age ≥ 18 years
- Antiretroviral naive
- HIV-1 RNA greater than 1,000 copies m/L
- Any CD4 cell count
- Not currently taking vitamin D or calcium or taking ≤ 800 IU of vitamin D and ≤ 500 mg of calcium daily

Study Regimen:

48 week, randomized, double-blind. Subjects will be randomly assigned to one of two groups:

Group A: TDF/FTC/EFV plus 4000 IU vitamin D daily and 500mg calcium twice daily

Group B: TDF/FTC/EFV plus vitamin D placebo and calcium placebo

A5272: STUDY TO DETECT THE PRESENCE OF HPV IN ORAL SECRETIONS

This is a prospective, observational study of HIV-1-infected adults who are starting antiretroviral therapy (ART) either through a clinical trial or as part of routine care, to explore the frequency of oral human papillomavirus (HPV) DNA shedding and oral warts after ART initiation.

- Be ART Naive
- Ready to initiate ART and must enter A5272 PRIOR to starting ART.
- Must not have ever received an HPV vaccine or have plans to receive an HPV vaccine within the next 6 months

SAILING: STUDY FOR HIV/AIDS TREATMENT EXPERIENCED INDIVIDUALS

- HIV+ men and women age ≥ 18 years
- Currently failing antiretroviral therapy
- Have developed resistance to at least two, but not all, HIV drug classes
- Never taken an integrase inhibitor (raltegravir, elvitegravir, or the study drug)

Study Regimen:

48 week, randomized, double-blind. Subjects will be randomized 1:1 to receive dolutegravir (DTG, GSK1349572), 50 mg once daily or raltegravir (RAL) 400 mg twice daily, each added to an investigator selected background regimen consisting of at least one fully active agent plus no more than one second single agent which may or may not be active.

VIKING: STUDY FOR HIV/AIDS INTEGRASE INHIBITOR EXPERIENCED INDIVIDUALS

- HIV+ men and women age ≥ 18 years
- HIV-1 RNA ≥ 500 copies/mL
- Experienced virological failure on raltegravir (RAL) or elvitegravir (ELV) regimen
- Developed resistance to at least one drug from each of three or more of all approved classes of ART
- ART-experienced, Integrase Inhibitor (INI)-experienced, DTG naïve

Study Regimen: 24 week, open label single arm study. The study will assess DTG 50mg twice daily administered initially with the current failing ART regimen but then with an optimized background ART regimen (OBR) after Day 7. All subjects who successfully complete 24 weeks of treatment will continue to have access to DTG until it is locally available as long as they continue to derive clinical benefit.

A5275: PILOT STUDY TO SEE IF ATORVASTATIN CAN DECREASE IMMUNE ACTIVATION AND INFLAMMATION

- Taking ART with a Protease Inhibitor (PI) for at least 6 months prior to study regimen
- HIV-1 RNA undetectable and D-dimer ≥ 0.25 $\mu\text{g/mL}$ (checked at screening)
- LDL cholesterol ≥ 70 and < 130 mg/dL and not on lipid-lowering therapy
- No current or past cancers, diabetes, or coronary artery disease
- No chronic active Hepatitis B or C

Study regimen:

Subjects will be randomized to receive atorvastatin or placebo while continuing their boosted, PI-based regimen. This regimen will continue through week 20 when a 4-week wash-out will occur. The subject will then enter the second (cross-over) 20-week treatment phase, receiving atorvastatin or placebo depending on the original assignment. At week 44 another 4-week wash-out will occur, with patient follow-up ending at week 48.

A5286: PILOT STUDY TO SEE IF RIFAXIMIN CAN DECREASE IMMUNE ACTIVATION AND INFLAMMATION

- CD4+ cell count ≤ 350 cells/mm³
- HIV-1 RNA undetectable
- Taking ART for at least 96 weeks prior to study.

Study regimen: Subjects will be randomized to receive rifaximin versus no study treatment for 4 weeks.

A5258: STUDY OF CHLOROQUINE FOR REDUCING HIV-ASSOCIATED IMMUNE ACTIVATION

- CD4+ cell count ≤ 350 cells/mm³
- HIV-1 RNA undetectable
- Taking ART for at least 24 months prior to study.
- Protease Inhibitors (PIs) are not allowed.

Study regimen: Crossover design: 12 weeks of chloroquine administration compared to placebo, followed by the reverse order.

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