



CORNELL CLINICAL TRIALS UNIT

Unlocking the mysteries of HIV Treatment

HIV TREATMENT STUDIES

INITIAL TREATMENT OF HIV-1 INFECTED INDIVIDUALS (ACTG 5257)

- Men and women age ≥ 18 years
- Antiretroviral-naïve (less than 10 days of antiretroviral treatment)
- HIV-1 RNA ≥ 1000 copies/mL
- Genotype demonstrating no evidence of any major NRTI or PI resistance-associated mutation
- Ability to obtain and fill a prescription for Ritonavir 100 mg QD

Study Regimen:

Arm A: ATV 300 mg QD + RTV 100 mg QD + FTC/TDF 200/300 QD

Arm B: RAL 400 mg BID + FTC/TDF 200/300 mg QD

Arm C: DRV 800 mg QD + RTV 100 mg QD + FTC/TDF 200/300 mg QD

STUDY FOR PEOPLE FAILING ANTI-HIV REGIMEN (OPTIONS – ACTG 5241)

- HIV RNA ≥ 1000 copies/ml
- Currently on a failing Protease Inhibitor (PI) regimen
- NRTI, NNRTI and PI experienced or resistance

Study regimen: Choice among: enfuvirtide, maraviroc, raltegravir, darunavir, tipranavir and etravirine. Subjects are randomized to either receive NRTIs or not.

STUDY OF CHLOROQUINE FOR REDUCING HIV-ASSOCIATED IMMUNE ACTIVATION (A5258)

- CD4+ cell count ≥ 400 cells/mm³; HIV-1 RNA $\geq 10,000$ copies/mL
- Not taking ART for at least 6 months prior to study entry, and not likely to start within the next 6 months.
- No use of chloroquine or hydroxychloroquine within 3 months prior to study entry.

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

HEPATITIS CO-INFECTION

NITAZOXANIDE IN ADDITION TO STANDARD HEPATITIS C TREATMENT FOR SUBJECTS CO-INFECTED WITH HIV (A5269)

- HCV genotype 1 only
- No prior HCV treatment or exposure to any interferon.
- Currently on stable antiretroviral therapy for 60 days prior to entry and no plans to change or stop ARVs during the first several months on study.
- CD4 >200 cells/mm³ – 90 days prior to entry
- Protocol specific laboratory values – 42 days prior to entry (notably hemoglobin ≥ 11 (men)/ ≥ 10 (women); ANC $> 1,000$, platelet $\geq 70,000$, creatinine $\leq 1.5 \times$ ULN)
- Any history of decompensated liver disease is exclusionary.
- Meets guidelines for birth control/contraception
- May not have any acute or opportunistic infections within 24 weeks prior to entry

Study regimen: Subjects will receive nitazoxanide (NTZ) for 4 weeks, followed by continued NTZ plus standard of care peginterferon alfa-2a and ribavirin for 48 weeks.

**PIO PRE-C - HEPATITIS C TREATMENT FOR PEOPLE CO-INFECTED WITH HIV
with Insulin Resistance and Prior Non-Response to Peginterferon/ribavirin treatment (ACTG 5239)**

- HCV Genotype 1 only
- **Nonresponder** to previous treatment with PEG-IFN alfa-2a 180 mcg/wk, or alfa-2b 1.5 mcg/kg/wk, and ≥ 1000 mg/d RBV given for at least 12 consecutive weeks.
- **Insulin resistance** is based on HOMA-IR value of >2.5 . (to be determined at screening)
- Currently on stable antiretroviral therapy for 12 wks prior to entry and no plans to change ARV's for at least 24 wks after entry, OR on no antiretroviral therapy and no plans to start therapy for 24 weeks after entry.
- No current ddl, AZT or oral hypoglycemic agents
- $CD4 >200$ cells/mm³

Study regimen:

Step 1: pioglitazone (30 mg tablet daily) for 24 to 28 weeks.

Step 2: pioglitazone (30 mg tablet daily), with PEG-IFN (alfa-2a180 mcg/wk) and RBV (1000-1200 mg/d) for up to additional 48 weeks depending on treatment response.

COMPLICATIONS, CO-INFECTIONS, ETC.

INVESTIGATIONAL PNEUMOCOCCAL VACCINE STUDY FOR HIV+ PEOPLE (WYETH 6115A1)

- HIV+ men or women ≥ 18 years
- On HAART for at least 6 month prior to study, or not on any current antiretroviral therapy.
- No active AIDS related illness, like infections or malignancies.
- No serious allergic reaction to any vaccine.
- Must have received polysaccharide pneumococcal vaccine (Pneumovax) at least once in the past but no previous vaccination with any conjugate pneumococcal vaccine.

Study regimen: All participants will receive three doses of the investigational vaccine.

Quadrivalent HPV (Types 6, 11, 16, 18) VACCINE STUDY FOR HIV+ WOMEN (ACTG 5240)

- HIV+ women age 13 to 45
- $CD4 \leq 200$ or HIV RNA $> 10,000$
- Must be on same HAART regimen for at least 12 weeks prior to study entry with no change within 30 days prior to study.
- No condyloma within the past 6 months
- All subjects receive HPV vaccine

Study regimen: All participants will receive three doses of the vaccine.

ZOSTER (SHINGLES) VACCINE FOR HIV+ PEOPLE (ACTG 5247)

- HIV+ men or women ≥ 18 taking potent ART
- $CD4$ count $\geq 200-350$ and undetectable HIV viral load; $CD4$ NADIR ≥ 100

Study regimen: Subjects will be randomized to receive ZOSTAVAX[®] or placebo (3:1) at entry and week 6.

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