



Research Study: ACTG 5209

A Pilot Study of the Safety, Efficacy, and Tolerability of Ezetimibe (Zetia) in Combination with Statin Therapy for the Treatment of Elevated LDL Cholesterol in HIV Positive Individuals

Brief Description

This is a blinded, cross-over study adding Ezetimibe (Zetia) to the Statin medication you currently are on for the treatment of high LDL ('bad') cholesterol. Blinded means that neither you nor your caregiver will know whether you are on real medication or a placebo. A placebo is like a sugar pill and does not contain any active medication. A cross-over study means that you will take ezetimibe for half of the study and a placebo for the other half of the study. **Duration of Study:** 28 weeks

Purpose of this Study

To learn how safe and how well tolerated it is to take Ezetimibe (Zetia) in combination with HIV and Statin medications in people who are HIV infected, and how well it works to lower LDL cholesterol.

Requirements to Enter Study

- Men and women who are 18 years of age or older
- Must have taken Statin and anti-HIV medications for at least the 3 months before entering study, and have had no changes in the way you take them for at least 30 days before entering study
- Must be on a diet and exercise program to help lower cholesterol for at least 30 days before entering study, and be willing to stay on this while on study
- Fasting blood work (only water for at least 8 hours) that shows an LDL of greater than or equal to 130
- Cannot have a history of diabetes mellitus, coronary heart disease, or congestive heart failure
- Cannot have taken ezetimibe in the past

Treatment

Arm A: Ezetimibe will be taken once a day for 12 weeks, followed by 4 weeks of not taking any study treatment, followed by 12 weeks of taking Placebo for Ezetimibe once a day.

Arm B: Placebo for Ezetimibe will be taken once a day for 12 weeks, followed by 4 weeks of not taking any study treatment, followed by 12 weeks of taking Ezetimibe once a day.

Examples of Possible Risks

Few effects of Ezetimibe have been reported. Side effects have included stomach pain and feeling tired. Ezetimibe may also interact with other medications that you take or may have other unknown effects.

Principal Investigator

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