

A5258 Participant Summary Sheet

A Phase II, Double Blind, Randomized, Exploratory Study of Chloroquine for Reducing HIV-Associated Immune Activation

Brief Description:

A5258 is a randomized, double-blind, placebo controlled study to evaluate the use of chloroquine in chronically infected patients who are not receiving antiretroviral therapy (ART).

Purpose of this Study:

- The purpose of this study is to learn how well chloroquine, an FDA approved medication used to treat malaria, reduces the level of activated CD8 T cells. Increased activation of CD8 T cells has been associated with progression of HIV disease.

Requirements to Enter Study:

- HIV infected male or female between the ages of 18-65
- CD4 count - 400 and above
- HIV viral load - 20,000 and above
- Not taking ART for at least 6 months prior to study and not likely to start within 6 months
- Not pregnant or breast-feeding

Treatment: There will be two treatment groups in this study:

- Group A: 12 weeks of chloroquine followed by 12 weeks of placebo (a look-alike pill that does not contain any drug).

OR

- Group B: 12 weeks of placebo followed by 12 weeks of chloroquine.

Which group you are assigned to is decided by chance, like the flip of a coin. You will have an equal chance of being assigned to either group.

Duration of Study: Up to 24 weeks of treatment with an additional 4 weeks of safety follow-up.

For more information contact:

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