



ACTG 5197

Antiretroviral Effect of Immunization with the MRK Ad5 HIV-1 gag Vaccine

Brief Description

This study will look at a group of 120 people who will be randomized 2 to 1 to receive the MRK Ad 5 HIV-1 vaccine or placebo. You will receive a series of three vaccines (or placebos) and will then begin a treatment interruption. If after the third vaccine, your viral load and T-cell counts are within a certain range, you will stop your anti-HIV medications for about 4 months. You will come to the clinic frequently for close monitoring.

Purpose of the Study

This study will compare the HIV viral load of people off anti-HIV drugs who have either received an HIV-vaccine or a vaccine placebo. Longer-term safety information about the HIV vaccine will also be collected.

Study Treatment

Study treatment is the MRK Ad5 HIV-1 vaccine or placebo. The study will not provide anti-HIV medications, but you will be required to be on ART during certain steps of this study. You will receive a series of three vaccines (or placebos) over the course of 26 weeks (at day 1, week 4 and week 26).

Duration of Study

The first 26 weeks will be the vaccination phase of the study, which will be followed by about 4 months of a treatment interruption. After this phase you may remain off antiretrovirals or restart them, but all participants will continue to be followed for 87 weeks to gather continuous safety data. On Step 5 of this study, your clinical status (T-cells, viral load, etc.) will be gathered once every six months for long term follow up.

Requirements to be in the Study

- HIV positive men or women ages 18 to 55 years of age.
- You must have been on a stable medication regimen for at least 4 weeks, and must have been on medications that have suppressed your virus for at least two years.
- The viral load must be less than 500 by two measurements. To be eligible for the study, your viral load must now be <50. Your T-cell counts needs to be >500.
- Ad5 neutralizing titer of less than 200 at screening – this will be determined by the study.
- You must be willing to undergo a treatment interruption.

Principal Investigator

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For more information, please call 310.206.6414