

NON-TECHNICAL ABSTRACT

This protocol will study up to 25 patients with HIV infection that have ≥ 200 CD4 cells/mm³, viral load ≤ 50 copies/ml on a stable regimen of highly active antiretroviral therapy. CD4+ T cells from HIV infected individuals will be modified *ex vivo* using an HIV vector called VRX496, which has been engineered to inhibit wt-HIV replication. This vector has been deleted of all of its HIV genes and cannot cause AIDS. Each subject will receive up to 2 cycles of 4 doses each of autologous VRX496-modified CD4 T Cells. Each infusion of a cycle will be given biweekly and last approximately 10 minutes. Subjects will be examined weekly during the treatment phase for safety. Follow-up examinations will be conducted at approximately monthly intervals up to 6 months, thereafter; long term follow-up will be performed annually for 15 years. The primary objective of this study is to establish the safety of multiple doses of VRX496-modified CD4+ T cells. Secondary objectives include assessing the persistence of the VRX496 vector in the body and assessing efficacy. The persistence and trafficking of the VRX496 cells will be assessed by rectal biopsy. To assess antiviral effects of the VRX496 cells, the patients will undergo structured treatment interruption.