

2. NON-TECHNICAL ABSTRACT

This protocol will study patients with HIV infection that have failed, are resistant to or have discontinued currently available drugs and therapies. In this protocol CD4 T cells from HIV infected individuals will be modified using an HIV vector called VRX496 that has been engineered to inhibit wt-HIV replication. The study will test for how long vector-transduced patient T cells survive in HIV infected patients. The HIV vector used has been deleted of all of its HIV genes and cannot cause AIDS. Since this protocol is a phase I clinical trial with the goals for evaluating the safety of the HIV vector, only one vector will be tested. In this study, four groups of patients will be studied: patients 1 to 3 will be given a transfusion of 1×10^9 CD4 T cells that have been modified with VRX496, the HIV-1 based anti-HIV-1 vector; patients 4 to 6 will be given a transfusion of 3×10^9 CD4 T cells that have been modified with VRX496; patients 7 to 9 will be given a transfusion of 1×10^{10} CD4 T cells that have been modified with VRX496; and patients 10 to 12 will be given a transfusion of 3×10^{10} CD4 T cells that have been modified with VRX496. The objective of this study is to establish the safety of this approach, specifically that there is no precipitous increase in wt-HIV viral load, no precipitous decrease in CD4 T cell count and no significant adverse effects related to the introduction of vector transduced cells into the patient.