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Background

The advent of highly active antiretroviral therapies (HAART) changed the course of human immunodeficiency virus (HIV) infection. However, HAART induces a large range of toxicities, highlighting the need for novel therapeutic strategies, such as an effective therapeutic vaccine. Vaccines act via dendritic cells (DCs), which induce, regulate and maintain immune responses.

Methods

In our view, three parameters are critical for the generation of potent *ex vivo*-generated DC vaccines for HIV patients: 1) antigen; 2) DC type; and 3) activation signal. With this in mind, we designed a clinical trial (IRB#008-017; BB-IND #13748) to test the safety and immune efficacy of a therapeutic HIV vaccine consisting of autologous DCs generated *ex vivo* from monocytes cultured with GM-CSF/IFN-alpha and loaded with five lipidated HIV antigens (LIPO5). Our trial exploits a combination of: 1) HIV-derived lipopeptides that cover nef, gag and pol epitopes – binding to >90% of HLA molecules and permitting presentation of T cell epitopes and generation of humoral immunity; 2) Interferon (IFN)-DCs, which demonstrate powerful priming functions *in vitro*; and 3) LPS activation, which enhances priming by IFN-DCs. Such a vaccine is expected to induce strong and diverse HIV-specific immune responses.

Results

This phase I clinical trial in 19 asymptomatic HIV-infected patients with undetectable viral load while treated with HAART will test the safety of DC vaccination and of analytical treatment interruption (ATI). Patients receive four monthly DC vaccinations in conjunction with antiretroviral therapy. Twelve weeks after the fourth vaccine, patients who meet the pre-specified criteria will stop HAART. ATI will last for up to six months.

Conclusion

The primary end point of the trial is safety. Secondary endpoints are immune, including: strength of HIV-specific CD4/CD8 responses, proportion of responders, and breadth of T cell responses. Immune responses will be assessed using IFN-gamma ELISPOT, polychromatic flow cytometry, EPIMAX and transcriptional profiling.