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Potent cellular immune responses after therapeutic immunization of HIV-positive patients with the PENNVAX®-B DNA vaccine in a Phase I Trial

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Background

Although highly active antiretroviral therapy (HAART) regimens have dramatically transformed treatment of HIV infection, achieving 95% adherence to HAART regimens is notoriously difficult. The successful creation of an immunotherapy for infection could eliminate the potential pitfalls associated with the necessity for long-term adherence to drug therapy. To that end, we evaluated the safety and immunogenicity of the PENNVAX®-B vaccine, delivered with in vivo electroporation (EP) in HIV-infected volunteers on HAART in a Phase I open-label study.

Methods

Enrollment criteria included HIV RNA<75copies/mL, CD4>400/μL with nadir >200/μL. Twelve eligible subjects received a 4 dose series (day 0, weeks 4, 8 and 16) of 3 mg PENNVAX®-B (consisting of SynCon® HIV Gag, Pol, and Env immunogens) intramuscularly followed by in vivo EP with the CELLECTRA®-5P device.

Results

All the enrolled subjects completed the immunization schedule. The vaccine demonstrated an acceptable safety profile and was generally well tolerated. Overall, 9 out of 12 subjects (75%) showed significant vaccine-specific T-cell responses in the form of IFN-γ ELISpot against at least one of the three vaccine antigens (Gag, Pol, or Env) following vaccination. Furthermore, responses were not dominated by a single antigen, as 50% of subjects had strong vaccine induced responses to at least 2 of the 3 antigens and 3 showed vaccine-induced responses to all 3 antigens. Importantly, the ELISpot responses induced by vaccination were predominantly CD8+T-cells, which are considered to be paramount in clearing chronic viral infections and an important measure of the performance of a therapeutic vaccine. Additionally, HIV-specific immune responses were assayed by flow cytometry to measure IFN-γ production by both CD4+ and CD8+T cells as well as co-expression of the CTL-related markers CD107a, GranzymeB and Perforin.

Conclusion

Analysis of these data should provide more definitive evidence of HIV-specific CTL function, which has been implicated in control of viral replication in HIV-infected patients.

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