AIDS Res Hum Retroviruses. 2008 Jun;24(6):873-80. doi: 10.1089/aid.2008.0292.

A phase 1 study to evaluate the safety and immunogenicity of a recombinant HIV type 1 subtype C adeno-associated virus vaccine.

Mehendale S[1], van Lunzen J, Clumeck N, Rockstroh J, Vets E, Johnson PR, Anklesaria P, Barin B, Boaz M, Kochhar S, Lehrman J, Schmidt C, Peeters M,Schwarze-Zander C, Kabamba K, Glaunsinger T, Sahay S, Thakar M, Paranjape R, Gilmour J, Excler JL, Fast P, Heald AE.

Author information

Abstract

A novel prophylactic AIDS vaccine candidate, consisting of single-stranded DNA for HIV-1 subtype C gag, protease, and part of reverse transcriptase genes, enclosed within a recombinant adeno-associated virus serotype-2 protein capsid (tgAAC09) induced T cell responses and antibodies in nonhuman primates. In this randomized, dose escalation phase I trial, HIV-uninfected healthy volunteers (50 in Europe, 30 in India) received a single intramuscular injection of tgAAC09 at 3 x 10(9) DNase resistant particles (DRP) (n = 16), 3 x 10(10) DRP (n = 23), 3 x 10(11) DRP (n = 25), or placebo (n = 16). Twenty-one participants in Europe received a second (boost) dose of 3 x 10(11) DRP tgAAC09 or placebo at least 24 weeks after the first injection. The vaccine was safe and well-tolerated after initial and boost vaccination. Local and systemic reactogenicity was experienced by 13-25% of participants and was not dose related. No vaccine-related serious adverse events were reported. Modest HIV-specific T cell responses were detected in 7/64 vaccinees (40-385 SFC/10(6) PBMC), with 16% (4/25) responders in the highest dose group. All responses were to Gag epitopes. tgAAC09 appears to be safe, well-tolerated, and modestly immunogenic. Further evaluation of higher doses of tgAAC09 and boost injections is ongoing in Africa.