

SAFETY AND IMMUNOGENICITY OF LIVE RECOMBINANT ALVAC-HIV (VCP1521) PRIMING WITH AN OLIGOMERIC GP160 BOOST IN THAI HIV-SERONEGATIVE ADULTS

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Background: An ALVAC-HIV candidate vaccine has been constructed with HIV-1 env (TH023), gag and pro (LAI) genes of clades E and B viruses (vCP1521) and an oligomeric gp160 protein derived from a Thai E isolate (TH023) for evaluation in Thailand.

Objective: To evaluate the safety, tolerability and immunogenicity of the prime-boost HIV vaccine combination ALVAC-HIV (vCP1521) and oligomeric gp160 (TH023) in HIV-seronegative, healthy Thai adults.

Methods: Phase I: open-label evaluation of ALVAC-HIV and of gp160 protein (Groups I and II, 5 subjects each). Phase II: double blind, randomized, placebo-controlled evaluation of the ALVAC prime and gp160 boost (Group III, 46/15 vaccine/placebo recipients). Injections were given IM at 0, 4, 12 and 24 weeks. Subjects were monitored for 7 days for reactogenicity. Sera were tested for binding/neutralizing Ab to subtype B and E antigens/virus; PBMCs for antigen-specific lymphoproliferation and CTL (by standard chromium release) responses.

Results: Local reactions were more frequent in vaccinees than placebo recipients but none required withholding of vaccinations due to reactions or intolerance. No significant clinical laboratory abnormalities related to vaccination were seen. There was one SAE but unrelated to vaccination. NAbs were detected in 27% against SF2 strain and 96% against subtype E strains in vaccinees. LPA responses developed in 76% and 89% to subtype B and E envelope antigens, respectively. CTL data are currently being analyzed.

Conclusion: The prime-boost vaccine combination of ALVAC-HIV (vCP1521)/oligomeric gp160 (TH023) from Aventis Pasteur appeared safe and well tolerated in healthy Thai adults. The safety profile was satisfactory for advancement to phase III evaluation. Good immunogenicity was shown by neutralization assay and LPA.

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