Retrovirology

BioMed Central

Oral presentation

OA05-01. *In vivo* electroporation enhances the immunogenicity of ADVAX, a DNA-based HIV-1 vaccine candidate, in healthy volunteers

S Vasan*[1], A Hurley[1], SJ Schlesinger[1], D Hannaman[2], DF Gardiner[1], DP Dugin[1], MM Boente-Carrera[1], RM Vittorino[1], M Caskey[1], J Andersen[1], Y Huang[1], J Cox[3], T Tarragona[3], DK Gill[3], H Cheeseman[3], L Clark[3], L Dally[4], C Smith[4], C Schmidt[3], H Park[3], E Sayeed[3], J Gilmour[3], P Fast[3], R Bernard[2] and DD Ho[1]

Address: [1]Aaron Diamond AIDS Research Center, Rockefeller University, New York, NY, USA, [2]ICHOR Medical Systems, San Diego, CA, USA, [3]International AIDS Vaccine Initiative, New York, NY, USA and [4]The EMMES Corporation, Rockville, MD, USA

* Corresponding author

from AIDS Vaccine 2009
Paris, France. 19–22 October 2009

Published: 22 October 2009

Retrovirology 2009, **6**(Suppl 3):O31 doi:10.1186/1742-4690-6-S3-O31

This abstract is available from: http://www.retrovirology.com/content/6/S3/O31

Background

In healthy volunteers, we sought to determine the safety, tolerability, and immunogenicity of ADVAX, a subtype B'/C, DNA-based, multigenic, HIV-1 vaccine candidate, when injected intramuscularly immediately followed by *in vivo* electroporation (EP) using the TriGrid™ Delivery System.

Methods

Forty healthy volunteers aged 18–60 were enrolled in a double blind randomized phase-I trial. Eight volunteers each received either low dose (LD, 0.2 mg); mid dose (MD, 1.0 mg); or high dose (HD, 4.0 mg) ADVAX or saline placebo via EP. Another eight volunteers received 4.0 mg ADVAX intramuscularly (IM). Vaccinations were given at weeks 0 and 8. The protocol was subsequently amended to administer a third dose of HD EP/placebo at week 36 to volunteers receiving either HD ADVAX via EP (n = 8) or placebo via EP (n = 3). Total study follow-up is 14 months.

Results

There have been no vaccine or device related serious adverse events to date. After two vaccinations in all subjects, the IFNg ELISPOT response rates were IM: 1/8 (13%), LD-EP: 3/8 (38%) MD-EP: 7/8 (88%) and HD-EP: 6/8 (75%). In the same order, the mean (range) response to peptide pools spanning all antigens was 72, 120 (70–193), 151 (53–440), and 141 (59–336) SFC/million PBMCs. The breadth of the response improved with EP and increasing dosage, with responses to 1, 1, 3, and 4 of the 4 ADVAX gene products. ICCS analysis of ELISPOT responders revealed a balanced CD4+/CD8+ response. There were no responses to placebo, by definition. An analysis of responses after the third vaccination in the high dosage group is ongoing.

Conclusion

This study is the first demonstration in healthy volunteers that EP *in vivo* is safe, tolerable, and effective in improving the magnitude and breadth of cellular immune responses to a DNA-based vaccine.