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Poster presentation

P14-12. Safety and tolerability of VRC DNA and rAd5 HIV-1 vaccine delivery by intramuscular, subcutaneous and intradermal administration in healthy adults

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Background

Safety and tolerability of the VRC/NIAID DNA and rAd5 HIV-1 vaccines administered by intramuscular (IM), subcutaneous (SC), and intradermal (ID) routes of administration were evaluated in VRC 011.

Methods

60 subjects (18–50 yrs) were randomized to 6 schedules. Group 1 (n = 30) received 3 DNA prime vaccinations (Wks 0,4,8) and Group 2 (n = 30) received a recombinant adenoviral vector (rAd5) prime vaccination (Wk 0). Both groups received rAd5 booster at Wk 24. Subjects were equally randomized to receive prime injections by IM, SC and ID routes. DNA dosage was 4 mg for IM and SC; 0.4 mg for ID injections. rAd5 dosage was 10^{10} PU by all routes. Half of the subjects in each group had pre-existing Ad5 neutralizing antibody.

Results

27/30 Group 1 subjects completed 3 DNA primes; 30/30 Group 2 subjects completed rAd5 prime by the assigned route. Local pruritis was reported following 3/30 DNA ID prime, 6/10 rAd5 ID prime and 2/10 rAd5 SC prime injections (but not after DNA SC, DNA IM or rAd5 IM injections). Superficial skin lesions were observed following 5/10 rAd5 ID injections. Small nodules at the injection site were reported following 1/30 DNA ID injections, 3/10 rAd5 ID injections and 2/10 rAd5 SC injections.

Conclusion

All routes were well tolerated. Local and systemic reactogenicity profiles were acceptable for additional studies. Local reactions for ID and SC injections had different characteristics compared to the IM injections, which have typically been used for these vaccines in prior phase I/II studies.