OA04-01. Safety and immunogenicity of LIPO-5, a HIV-1 lipopeptide vaccine: results of ANRS VAC18, a phase 2, randomized, double-blind, placebo-controlled trial

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Background

ANRS HIV-LIPO-5 vaccine includes 5 long peptides, Gag17–35, 253–284, Pol325–355, Nef66–97 and 116–145, containing multiple CD8+ and CD4+ T-cell epitopes, coupled to a palmytoil tail. Phase 1 studies have shown that vaccine dosage at 500 μg/lipopeptide elicits cellular immune responses. Whether HIV-LIPO5 immunogenicity varies with the dosage is unknown.

Methods

One hundred and thirty two 21- to 55-year-old HIV negative volunteers, enrolled in 6 HIV-vaccine clinical sites, were randomized to receive either the HIV-LIPO-5 vaccine at 50 μg/lipopeptide (N = 32; LIPO-5 50), 150 μg (N = 32; LIPO-5 150), 500 μg (N = 33; LIPO-5 500) or placebo (N = 34). Vaccinations were given IM at weeks 0, 4, 12 and 24. HIV-1 specific CD8+ (IFN-gamma ELISpot on PBMC cultured 12-days) and CD4+ responses (PBMC lymphoproliferation) were assessed at baseline, two weeks after each injection, and at week 48.

Results

No adverse events attributable to vaccine were noted throughout the study. Local reactions appeared dose-dependent; no differences in systemic reactions were observed between groups. Sustained (at least on 2 separate occasions) CD8+ response rates to at least one HIV-1 pool were: 5/32 (16%) for placebo, 22/32 (69%) for LIPO-5 50, 21/33 (64%) for LIPO-5 150 and 21/34 (62%) for LIPO-5 500 groups ($P \leq .0001$ for all comparisons to placebo). Cumulative CD4+ response rates were: placebo: 2/32 (6%), LIPO-5 50: 15/32 (47%), LIPO-5 150: 18/33 (55%) and LIPO-5 500: 15/34 (44%) ($P < .0001$ for all comparisons to placebo). The majority of CD4+ (75%) and CD8+ (60%) responses were directed towards Gag253–284. CD8+ responses against Nef, Pol were noted in 36% and 33% of vaccinees, respectively. At week 48, CD8+ responses persisted in 47/91 (52%) HIV-LIPO-5 recipients.

Conclusion

ANRS VAC18 shows that low and high doses of HIV-LIPO-5 vaccine elicit sustained CD8+ and CD4+ T-cell responses. According to the good tolerance of the vaccine,

the lowest dose of 50 μg appears as the most appropriate to be used in further trials.