Comparison of Immunogenicity and Safety of Four Doses and Four Double Doses vs. Standard Doses of Hepatitis B Vaccination in HIV-infected Adults: A Randomized, Controlled Trial

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Background: HBV vaccination is recommended in HIV-infected adults with CD4+ cell count >200/μL although the efficacy is only 33.3%-65%. We conducted a randomized, controlled trial to evaluate the efficacy and safety of three regimens of HBV vaccination at Chiang Mai University Hospital, Thailand.

Methods: From February 4, 2011 to May 4, 2012, 132 HIV-infected adults who had CD4+ cell counts >200 cells/μL, undetectable plasma HIV-1 RNA, and were negative for all HBV markers were 1:1:1 randomly assigned to receive one of three recombinant vaccine (Hepavax-Gene® Berna, Korea) regimens: 20 μg IM at months 0, 1, and 6 (Standard doses group, n=44), 20 μg IM at months 0, 1, 2, 6 (Four doses group, n=44), or 40 μg IM at months 0, 1, 2, and 6 (Four double doses group, n=44). The primary outcomes were to compare the immunogenicity and safety between the four doses and four double doses groups with the Standard doses group.

Results: At months 7 and 12, the percentages of responders with anti-HBs ≥ 10 mIU/mL were 88.6% and 70.4% in the Standard doses group, 93.2% and 86.4% in the four doses group, (P=0.713 and 0.119), and 95.4% and 88.6% in the four double doses group, (P=0.434 and 0.062), respectively. Fifty-seven participants (43.2%) reported adverse events. The most common adverse event was pain at the injection site (42.4%); this was significantly more frequent in the four double doses group (56.8%) compared to the Standard doses group (29.5%, P=0.017). No serious adverse events were observed.

Conclusions: In Northern Thailand, the standard three-doses HBV vaccination in HIV-infected adults with CD4+ cell counts >200 cells/μL and undetectable plasma HIV-1 RNA is highly effective. However, regimens of four injections of either standard or double doses may increase the response rate, induce higher level of antibody, and have longer immunoprotection.

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