Atsuko Hata et al., J Vaccines Vaccin 2014, 5:5
http://dx.doi.org/10.4172/2157-7560.S1.021

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Vaccines & Vaccination
September 24-26, 2014 Valencia Convention Centre, Spain

Double-blind randomized placebo-controlled trial to evaluate cell-mediated immunity and safety of the herpes zoster vaccine in elderly patients with diabetes

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Objective: To compare varicella zoster virus-specific cell-mediated immunity and humoral immunogenicity against the herpes zoster vaccine and placebo.

Methods: A double-blind, placebo-controlled, randomized trial of herpes zoster vaccine effects in elderly people with diabetes mellitus was conducted during May 2012 - November 2013 at Kitano Hospital, Osaka, Japan. People aged 60-75 years with diabetes with 6-9.5% HbA1c levels were eligible for enrollment; immunocompromised individuals were excluded. Participants received either the herpes zoster vaccine (Live Varicella Vaccine; BIKEN, The research foundation for Microbial Diseases of Osaka University, Japan) or placebo (0.5-mL dose) subcutaneously. They simultaneously received one dose of 0.5 ml of the 23-valent pneumococcal polysaccharide vaccine subcutaneously to promote participation. A varicella skin test, interferon-gamma enzyme-linked immunospot assay (ELISPOT), and immunoadherence hemagglutination (IAHA) test were performed before and 3 months after vaccination. ELISPOT counts are shown as spot-forming cell (SFC) per 106 PBMC. Vaccine safety was assessed using questionnaires for 42 days along with data of development of zoster obtained during the one year observational period.

Results: Participants were 29 (56%) male and 23 female patients with respective mean ages of 65.8 and 66.8 years. Mean skin test score differences from before to 3 months after immunization in placebo and vaccine group were, respectively, 0.1+-0.2 S.E. and 0.4 +-0.2 S.E. (no significant difference). Ratios of SFC after 3 months to before vaccination in placebo and vaccine group were, respectively, 1.0±0.0 and 1.1±0.0 The mean antibody titer in the IAHA increased approximately two-fold after vaccination in each group (no significant difference). No one developed herpes zoster during the one-year observational period. No systemic adverse reaction was found.

Conclusion: The herpes zoster vaccine boosted virus-specific, cell-mediated, and humoral immunity of elderly people with diabetes as well as placebo. The herpes zoster vaccine was used safely.

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