Immunogenicity and safety of a trivalent inactivated influenza vaccine

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Abstract

Background  Trivalent activated influenza vaccine (TIV) containing antigens to two influenza A strains, A(H1N1) and A(H3N2), and one influenza B strain, are the standard formulation for influenza prevention. The vaccines must be updated annually to provide optimal protection against the predicted prevalent strains for the next influenza season.

Objective  To assess the immunogenicity and safety of the inactivated influenza vaccine (Flubio) in adolescents and adults, 28 days after a single dose.

Methods  In this experimental, randomized, single-blind, bridging study, we included 60 healthy adolescents and adults. A single 0.5 ml dose was administered intramuscularly in the deltoid muscle of the arm. Blood samples were obtained before and 28 days after immunization. Standardized hemagglutination inhibition (HI) was used to assess antibody response to influenza antigens.

Results  From January to February 2010, a total of adolescents and adults enrolled in the study, but two participants did not provide the required blood samples. One hundred percent of the subjects has an anti-influenza titer ≥ 1:40 HI units to all three strains, A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2) and B/Brisbane/60/2008 (P= 1.000) after immunization. The Geometric Mean Titers (GMT) after immunization increased for all strains: A/Brisbane, 76.4 to 992.7, A/Uruguay, 27.6 to 432.1, and B/Brisbane, 19.9 to 312.7. Twenty eight days after immunization, we found a ≥ 4 times increase in antibody titers in 75.8% for A/Brisbane, 84.5% for A/Uruguay, and 77.6% for B/Brisbane. We also observed that 100% of seronegative subjects converted to seropositive for all 3 strains. All vaccines were well-tolerated. There were no serious adverse events reported during the study.

Conclusion  In adolescent and adults, the Flubio vaccine was immunogenic and safe (Pediatr Indones 2011, 51:22-8)