

A Novel Influenza A (H1N1) Vaccine in Various Age Groups

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As an answer to the novel influenza pandemic, China developed and recently approved for sale a new vaccine against the influenza virus strain A/California/07/2009 (H1N1). The presented study is a randomized, double blind, placebo controlled one, which evaluates the safety and immunogenicity profile of this monovalent influenza vaccine. In addition, the investigators evaluated the role of alum adjuvant in the vaccine formulation, the optimal amount of antigen and the need for second doses in children and elderly.

The study enrolled 2200 subjects, with ages between 3 and 77 years, divided in 4 age groups (3-11, 12-17, 18-60 and over 60 yrs). All subjects received two doses of vaccine at 21 days interval. The subjects were randomized to receive placebo or active vaccine, with or without alum adjuvant, in doses of 7.5, 15 or 30 μ g. The primary immunologic endpoints were the proportion of subjects with an increase in the hemagglutination-inhibition titer by 4 or more on day 21 after the first dose and on day 35 (14 days after the second dose). The primary safety end points were the presence of any systemic reaction or injection-site reaction

21 days after the first dose and 14 days after the second dose.

Results: There were no severe adverse reactions to the vaccine in any of the studied subgroups. Most of the systemic and injection-site reactions were mild. In the subgroup with 15 μ g vaccine without alum adjuvant the hemagglutination-inhibition titer $\geq 1:40$ was reached until day 21 by: 74.5% of the subjects aged 3-11, 97.1% of those aged 12-17 and 18-60 and 79.1% of the subjects over 60 yrs. At day 35 the above mentioned titer was reached by 98.1%, 100%, 97.1% si 93.3%. The proportion of subjects reaching the titer of over 1:40 was even higher in the 30 μ g subgroup. The vaccine without alum adjuvant was associated with lower local reactions and more important immune answer than the vaccine with adjuvant.

The presented data suggest that an unique dose of vaccine without alum adjuvant, optimal of 15 μ g, induces a typical protective immune response in the majority of subjects aged between 12 and 60. In those under 12 or over 60 yrs immune responses were lower, suggesting the need of a second dose. The potential adverse reactions to this second dose need further evaluation.

Comment on a paper:

FC. Zhu, H. Wang, HH.Fang, JG.Yang, XJ Lin, XF Liang et al – A Novel Influenza A (H1N1) Vaccine in Various Age Groups. *N Engl J Med* 2009; 361: published online on 21. Oct. 200