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Title: **Safety and Cross-Reactive Immunogenicity of Two H5N1 A/Indonesia/5/2005 (Clade 2.1) AS-Adjuvanted Prepandemic Candidate Influenza Vaccines: A Phase I/II Clinical Trial**

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Abstract: Prepandemic H5N1 vaccines should be antigen-sparing, have acceptable reactogenicity and offer cross-reactive immunity to non-vaccine strains. Most clinical studies have evaluated clade 1 strains which infected humans in 2004-2005, while clade 2 strains have infected humans since 2005. We evaluated two H5N1 vaccine candidates made with a clade 2.1 strain. The vaccine candidates, produced at 2 sites (Dresden [D], Quebec [Q]) by 2 distinct processes, were made with A/Indonesia/5/2005 (clade 2.1) antigens. Adults (18-64 years) were vaccinated twice, 21 days apart, with 3.8µg of hemagglutinin (HA) with an oil-in-water emulsion-based Adjuvant System (AS) or without (control). 150 subjects received AS-adjuvanted D- or Q-antigens, while 75 control subjects received a non-adjuvanted Q-antigen. At days 0, 21 and 42, sera were tested for hemagglutination-inhibiting (HI) antibody against A/Indonesia/5/2005 and A/Vietnam/1194/2004 (Clade 1). Solicited local and general symptoms, unsolicited adverse events (AEs) and serious adverse events (SAEs) were recorded. (110028/NCT00510874). Although injection site pain was more frequent in the AS-adjuvanted vaccine groups, redness and swelling occurred in <5% of subjects. General symptoms (day 0-6) were more frequent in the AS vaccine groups but fever was uncommon (≤2%). All AEs decreased after dose 2. Clinical laboratory values and unsolicited AEs raised no safety concerns. No vaccine-related SAEs occurred. After dose 1, A/Indonesia seroconversion rates (SCR) reached 42.1%-45.7% in the AS vaccine groups (control:6.7%). After dose 2, SCR and the percent of subjects with HI titers ≥40 were 96.4%-97.2% in the AS vaccine groups (control:17.3%). Homologous HI GMT was enhanced ≥44-fold in the pooled AS vaccine group. After 2 doses, SCR to Clade 1 A/Vietnam/1194/04 was 56.4%-62.1% for the AS vaccine groups. At an antigen-sparing dose, the AS-adjuvanted A/Indonesia/05/2005 vaccines were markedly immunogenic against the vaccine strain and a Clade 1 strain. Reactogenicity was increased but acceptable, and no other safety concerns were identified.

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