Safety and immunogenicity of an MF59 (R)-adjuvanted A/H1N1 pandemic influenza vaccine in children from three to seventeen years of age

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Abstract

Objectives

This study was designed to identify the optimal dose of an MF59®-adjuvanted, monovalent, A/H1N1 influenza vaccine in healthy paediatric subjects.

Methods

Subjects aged 3–8 years (n = 194) and 9–17 years (n = 160) were randomized to receive two primary doses of A/H1N1 vaccine containing either 3.75 μg antigen with half a standard dose of MF59 adjuvant, 7.5 μg antigen with a full dose of MF59, or (children 3–8 years only), a non-adjuvanted 15 μg formulation. A booster dose of MF59-adjuvanted seasonal influenza vaccine including homologous A/H1N1 strain was given one year after priming. Immunogenicity was assessed by haemagglutination inhibition (HI) and microneutralization assays. Vaccine safety was assessed throughout the study (up to 18 months).

Results

A single priming dose of either MF59-adjuvanted formulation was sufficient to meet the European licensure criteria for pandemic influenza vaccines (HI titres ≥1:40 > 70%; seroconversion > 40%; and GMR > 2.5). Two non-adjuvanted vaccine doses were required to meet the same licensure criteria. After first and second doses, percentage of subjects with HI titres ≥1:40 were between 97% and 100% in the adjuvanted vaccine groups compared with 68% and 91% in the non-adjuvanted group, respectively. Postvaccination seroconversion rates ranged from 91% to 98% in adjuvanted groups and were 68% (first dose) and 98% (second dose) in the non-adjuvanted group. HI titres ≥1:330 after primary doses were achieved in 69% to 90% in adjuvanted groups compared with 41% in the non-adjuvanted group. Long-term antibody persistence after priming and a robust antibody response to booster immunization were observed in all vaccination groups. All A/H1N1 vaccine formulations were generally well tolerated. No vaccine-related serious adverse events occurred, and no subjects were withdrawn from the study due to an adverse event.

Conclusions

An MF59-adjuvanted influenza vaccine containing 3.75 μg of A/H1N1 antigen was well tolerated and sufficiently immunogenic to meet all the European licensure criteria after a single dose in healthy children 3–17 years old.