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Title	**Open-Label, Randomized, Parallel-Group, Multicentre Study to Evaluate the Safety, Tolerability and Immunogenicity of an AS03B/Oil-In-Water Emulsion- Adjuvanted (AS03B) Split-Virion Versus Non-Adjuvanted Whole-Virion H1N1 Influenza Vaccine in UK Children 6 Months to 12 Years of Age**
Agency	**NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
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Aim

To evaluate the safety, tolerability, and immunogenicity of an AS03B/oil-in-water emulsion-adjuvanted (AS03B) split-virion versus nonadjuvanted whole-virion H1N1 influenza vaccine in UK children aged 6 months to 12 years.

Conclusions and results

Among 937 children receiving vaccine, per-protocol seroconversion rates were higher after the AS03B-adjuvanted vaccine than after the whole-virion vaccine (98.2% vs 80.1% in children <3 years, 99.1% vs 95.9% among those aged 3-12 years), as were severe local reactions (3.6% vs 0.0% in those <5 years, 7.8% vs 1.1% in those aged 5-12 years), irritability in children <5 years (46.7% vs 32.0%), and muscle pain in older children (28.9% vs 13.2%). The second dose of the adjuvanted vaccine was more reactogenic than the first, especially for fever >38.0°C in those <5 years of age (22.4%vs 8.9%). The adjuvanted vaccine, although reactogenic, was more immunogenic, especially in younger children, indicating the potential for improved immunogenicity of influenza vaccines in this age group.

Recommendations

In this first direct comparison of an AS03B-adjuvanted split-virion vaccine versus whole-virion nonadjuvanted H1N1 vaccine, the adjuvanted vaccine – while reactogenic – was more immunogenic, especially in younger children, indicating the potential for improved immunogenicity of influenza vaccines in this age group.

Methods

The safety, reactogenicity, and immunogenicity of a tocopherol/oil-in-water emulsion-adjuvanted (AS03B) egg culture-derived split-virion H1N1 vaccine and a nonadjuvanted cell culture-derived whole-virion vaccine, given as a two-dose schedule, 21 days apart, were compared in a randomized, open-label trial of children aged 6 months to 12 years. Local reactions and systemic symptoms were collected for 1 week postimmunization, and serum was collected at baseline and after the second dose.

Further research/reviews required

See Executive Summary link www.hta.ac.uk/2225.

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