A randomised, single-blind, dose-range study to assess the immunogenicity and safety of a cell-culture-derived A/H1N1 influenza vaccine in adult and elderly populations

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BACKGROUND: Modern cell-culture production techniques and the use of adjuvants helps to ensure that the global demand for pandemic influenza vaccine can be met. This study aimed to assess the immunogenicty and safety profiles of various cell-culture-derived A/H1N1 pandemic vaccine formulations in healthy adult and elderly subjects. METHODS: Adult (18-60 years) subjects (n=544) received vaccine either containing 3.75mug of antigen with half the standard dose of MF59((R)) (Novartis Vaccines and Diagnostics) adjuvant, 7.5mug antigen with a full dose of MF59, or a non-adjuvanted vaccine containing 15mug of antigen. Elderly (</=61 years) subjects (n=268) received either the 3.75mug or 7.5mug adjuvanted formulations. Two priming vaccine doses were administered 3 weeks apart, followed by a single booster dose of seasonal influenza vaccine 1 year later. Immunogenicity was assessed 3 weeks after each vaccination. The safety profile of each formulation was evaluated throughout the study. RESULTS: A single primary dose of each A/H1N1 vaccine formulation was sufficient to meet all three European (CHMP) licensure criteria for pandemic influenza vaccines in adult subjects. Two licensure criteria were met after one vaccine dose in elderly subjects; two primary doses were required to meet all three criteria in this age group. The highest antibody titres were observed in response to the 7.5mug vaccine containing a full dose of MF59 adjuvant. All subjects rapidly generated seroprotective antibody titres in response to booster vaccination. CONCLUSION: This study identified one 3.75mug vaccine dose containing half the standard dose of MF59 adjuvant as optimal for adults, two doses were optimal for elderly subjects. The antigen-sparing properties of MF59, and rapid, modern, cell-culture production techniques represent significant steps towards meeting the global demand for influenza vaccine

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