

World-first swine-flu vaccine trial reveals one dose provides 'strong immune response'

September 3 2009

Results from the first swine-flu vaccine trials taking place in Leicester reveal a strong immune response after just one dose.

The pilot study, run by the University of Leicester and Leicester Hospitals, was trialled with 100 healthy volunteers, aged between 18 and 50.

Dr Iain Stephenson, who led the trial at the Leicester Royal Infirmary, said: "The clinical trial of [Novartis](#) MF59-adjuvanted cell-based A (H1N1) vaccine indicates that the "swine flu" vaccine elicits a strong [immune response](#) and is well-tolerated.

"Results showed that the serum antibody responses were highest among subjects who received two doses of vaccine, however a single vaccine dose also induced responses associated with protection against influenza.

"The findings showed that it is possible to induce protective antibody against A(H1N1) infection within two weeks of administration of a single low-dose adjuvanted vaccine."

Non-adjuvanted formulations were not evaluated in this part of the study and will be evaluated shortly

The trial evaluated the tolerability and [immunogenicity](#) of the vaccine, and tested different schedules of vaccination, in terms of time between vaccinations. The vaccine schedule was one or two doses of 7.5µg

MF-59 adjuvanted surface-antigen A/California/2009 vaccine derived from cell-culture.

Dr. Stephenson, of the Department of Infection, Immunity and Inflammation at the University of Leicester is a clinical senior lecturer at the University, and a consultant in infectious diseases at the University Hospitals of Leicester NHS Trust. He said: "The aim of the trial was to find out how many doses and what type of vaccine is needed to give protection. These initial results should help to plan vaccination campaigns in the autumn, including doses and timings. We concluded that the MF59-adjuvanted A(H1N1) vaccine of low antigen content was well tolerated and generated antibody responses associated with protection against [influenza](#), even after a single dose."

"The results suggest that one vaccine dose may be sufficient to protect against the A(H1N1) swine flu, rather than two. Larger trials are already underway around the world. Timings on when the vaccine will be available to governments will depend on the results of these clinical trials, and approvals by regulatory authorities"

The research found the vaccine is well tolerated with pain at the injection site the most frequent adverse event.

Additional pivotal trials with both cell culture and traditional egg based vaccines under way around the world that will include more than 6000 adults and children.

Previous research had indicated that two doses of the vaccine would be needed against swine [flu](#). You can access earlier stories here:

Source: University of Leicester ([news](#) : [web](#))

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