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A population based cohort study to assess the safety of pandemic influenza vaccine Focetria(®) in Emilia-Romagna region, Italy-Part Two.

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Abstract

INTRODUCTION: A two phases post authorization safety and effectiveness study of individuals vaccinated with the MF59-adjuvanted A/H1N1 influenza vaccine, Focetria(®) (Novartis Vaccines & Diagnostics, Siena, Italy), was conducted in Emilia-Romagna region, Italy during the 2009 A/H1N1 influenza pandemic. The second phase study aim was to detect short- and long-term adverse events of special interest (AESIs) following vaccination, and to measure vaccine effectiveness in term of hospital admissions.

STUDY DESIGN AND METHOD: A population-based cohort study using record linkage of automated healthcare databases is described. Focetria(®) was administered to 127,522 subjects between October 2009 and February 2010. Vaccinated subjects were generally less healthy than unvaccinated ones. Propensity to be vaccinated was calculated for each subject, and vaccinated and unvaccinated subjects were matched accordingly (103,642 subjects in each group). AESIs were validated against clinical records.

RESULTS: In the overall (pre-matching) cohort, a total of 504 short-term incident AESIs (28 in 127,522 vaccinated and 476 in 3,967,917 unvaccinated subjects) were registered (unadjusted OR: 1.8; 95% CI: 1.2, 2.7). No fatalities were recorded. In the matched cohort, a total of 26 short-term incident AESIs (11 in the vaccinated and 15 in the unvaccinated group) were registered, with no differences between groups (OR: 0.7; 95% CI: 0.3, 1.6). Most frequent short-term incident AESIs were convulsions (4 out of 11), and demyelinating diseases (3 out of 11). In the long-term a total of 121 incident AESIs (60 in the vaccinated and 61 in the unvaccinated group) were registered, with no differences between groups (OR: 1.0; 95% CI: 0.7, 1.4). Most common long-term incident AESIs were demyelinating diseases (21 out of 60), and vasculitis (13 out of 60). Vaccine effectiveness was not assessed as the majority of subjects were vaccinated at the end of the pandemic peak and few cases (<0.1%) had laboratory confirmation.

CONCLUSIONS: This population-based cohort study using automated databases suggests that Focetria(®) is not associated with an increase in AESIs.