

primary studies - published RCT

## **Comparison of immunogenicity and safety of a virosome influenza vaccine with those of a subunit influenza vaccine in pediatric patients with cystic fibrosis.**

**Code:** PM10770746

**Year:** 2000 **Date:** 2000

**Author:** Schaad UB

### **Study design (if review, criteria of inclusion for studies)**

open randomised multicentre study over 4 weeks.

### **Participants**

Children with CF (n = 64) in 5 paediatric centres in Switzerland.

### **Interventions**

A trivalent virosomal influenza vaccine (ASingapore/6/86 (H1N1); A/Shandong/9/93 (H3N2) B/Panama/45/90) (given as either single or 2 doses 4 weeks apart) versus a trivalent subunit influenza vaccine (A/Singapore/6/86 (H1N1); A/Shandong/9/93 (H3N2); B/Pana

### **Outcome measures**

1. Adverse effects 2. Antibody level rise

### **Main results**

Both vaccines induced comparable HI antibody titers. Seroconversion (> or =4-fold rise in HI antibody titers, reaching a titer of > or =1:40) was achieved in 41 to 100% of the participants. Seroprotection (HI titer, > or =1:40) and a >2.5-fold increase in geometric mean titers were achieved in 100% of the participants. Thus, all three EMEA requirements for influenza vaccine efficacy were met by all treatment groups and for both vaccines. The virosome vaccine, when administered as a single dose, seemed to induce superior immunogenicity compared with the standard pediatric two-dose regimen. Totals of 42 and 57% of vaccinees receiving virosome and subunit vaccines, respectively, reported at least one local AE (predominantly pain). Totals of 84 and 71% of subjects receiving virosome and subunit vaccines, respectively, complained in response to questions of at least one systemic AE (mainly cough, fatigue, coryza, or headache). The majority of events were mild or moderate and lasted 1 or 2 days only. No obvious relationship was found between AE reporting rate and vaccine formulation, age group, or dose regimen. The relatively high AE reporting rate seemed to be partly related to the symptomatology of the underlying CF disease.

### **Authors' conclusions**

In summary, the virosome and subunit vaccines induced in both age groups and against all three influenza strains an efficient immune response and were well tolerated by the children and adolescents with CF.

<http://dx.doi.org/10.1128/AAC.44.5.1163-1167.2000>

### **See also**

Antimicrob Agents Chemother. 2000 May;44(5):1163-7.

### **Keywords**

Adolescent; Adult; Child; Immunization; Infant; Infection; Influenza A virus; pharmacological\_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; Virus;