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primary studies - published RCT

## **Purified fusion protein vaccine protects against lower respiratory tract illness during respiratory syncytial virus season in children with cystic fibrosis.**

**Code:** PM8684872

**Year:** 1996 **Date:** 1996

**Author:** Piedra PA

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

double blind, placebo-controlled study

### **Participants**

17 CF children (mean age 4.5 years) treated, 17 CF children (mean age 5.8 years) non treated

### **Interventions**

children received PFP-2 vaccine or a saline vaccine.

### **Outcome measures**

At enrollment the Shwachman clinical score, Brasfield radiographic score, oxygen saturation (SpO<sub>2</sub>), anthropometric indices and other variables were recorded. After vaccination the reactions were assessed daily for 7 days. During the RSV season weekly telephone interviews were performed and children with an acute respiratory illness were evaluated and cultured for RSV. Serum was drawn before vaccination, 1 month after vaccination and at the end of the RSV season and tested for antibodies to RSV.

### **Main results**

Other than age the baseline measurements at enrollment were similar between groups. The PFP-2 vaccine produced mild local reactions and induced a significant neutralizing antibody response in two-thirds of the vaccinees and a significant enzyme-linked immunosorbent assay-fusion glycoprotein antibody response in nearly all the PFP-2 vaccinees. Vaccine-enhanced disease was not observed in PFP-2 vaccines infected with RSV. Protection against RSV infection was not observed; however, a significant reduction (t test, P

### **Authors' conclusions**

Efficacy of the PFP-2 vaccine against lower respiratory tract illness during the RSV season was shown in RSV-seropositive children with CF.

<http://dx.doi.org/10.1097/00006454-199601000-00006>

### **See also**

The Pediatric infectious disease journal YR: 1996 VL: 15 NO: 1

### **Keywords**

Child; fusion; Immunization; Infant; Infection; pharmacological\_intervention; placebo; Proteins; Respiratory Syncytial Virus Infections; Respiratory Tract Diseases; Respiratory Tract Infections; Virus; Bronchiolitis;