

primary studies - published RCT

## **Randomised trial of pivampicillin plus pivmecillinam vs. pivampicillin in children and young adults with chronic obstructive pulmonary disease and infection with haemophilus influenzae**

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

Randomised, single-blind comparative trial

### **Participants**

Recurrent and chronic lung infections with *Haemophilus influenzae* in patients with chronic obstructive pulmonary disease (COPD) or cystic fibrosis (CF). Fifty-six children and young adults with COPD or CF were randomised to the clinical study.

### **Interventions**

The patients were allocated at random to receive perorally either pivmecillinam, 40 mg/kg/day, combined with pivampicillin, 50 mg/kg/day, or pivampicillin 50 mg/kg/day alone for 14 days. A crossover pharmacokinetic study using the same drugs was carried out in 10 CF patients to determine the antibiotic concentrations in serum and sputum after a single dose of each drug.

### **Outcome measures**

Clinical scoring, lung function tests or adverse events. Follow-up microbiological evaluation 2 and 6 weeks after the end of treatment. Reinfection with another biotype. In the pharmacokinetic study, median peak serum concentration.

### **Main results**

The clinical study showed no significant differences in clinical scoring, lung function tests or adverse events after treatment with pivampicillin plus pivmecillinam or pivampicillin alone. Follow-up microbiological evaluation 2 and 6 weeks after the end of treatment showed that the offending pathogen was eradicated in 68% of the patients treated with pivampicillin plus pivmecillinam and in 67% of the patients treated with pivampicillin alone. Reinfection with another biotype was more common in the combination group (50% vs. 21%) than in the pivampicillin group. In the pharmacokinetic study the median peak serum concentration occurred two hours after intake of tablets.

### **Authors' conclusions**

The efficacy of double (beta)-lactam treatment in lung infections with *H. influenzae* appears to be equivalent to that of ampicillin on clinical lung symptoms, lung function tests, adverse effects and bacteriology.

<http://dx.doi.org/10.1185/03007999909116501>

### **See also**

Curr Med Res Opin. 1999;15(4):300-9.

### **Keywords**

Anti-Bacterial Agents; pharmacological\_intervention; Pivampicillin; Bacterial Infections; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Penicillins;