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

Code: PM10640263 **Year:** 1999 **Date:** 1999 **Author:** Johansen, H.K.

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;