

primary studies - published RCT

## **Alternative antibiotics against Pseudomonas infections in cystic fibrosis. In vitro activity, pharmacokinetics, and double-blind randomized clinical trial with azlocillin, piperacillin, cefoperazone, ceftazidime, cefsulodin, cefotaxime and moxalactam. Preliminary results.**

**Code:** CN-00174469

**Year:** 1983 **Date:** 1983

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

double-blind RCT

### **Participants**

100 CF patients selected on the basis of clinical and bacteriological criteria divided were divided into five treatment groups

### **Interventions**

Daily dosage of drugs, given i.v. as three divided doses, was as follows: penicillins 400 mg/kg, cephalosporins 200 mg/kg. Duration of therapy was 10-15 days.

### **Outcome measures**

The side-effects were evaluated. The pharmacokinetics of three antibiotics (axiocillin, cefotaxime and cefoperazone) were also evaluated by determination of serum and sputum concentrations after single-dose injection during treatment. The antibiotics were tested in vitro by an agar dilution technique; MICs were assessed against strains of Pseudomonas spp. and Pseudomonas aeruginosa isolation from CF patients. Results were evaluated by means of clinical score, chest X-ray score and bacteriological score.

### **Main results**

On the basis of in vitro testing, the highest sensitivity, both of Pseudomonas aeruginosa and Pseudomonas spp., was observed with ceftazidime, followed by piperacillin, azlocillin, cefsulodin and cefoperazone; cefotaxime and moxalactam showed lower activity rates and were therefore removed at an early stage from the trial. Preliminary clinical results indicated the following tendencies: 1) the best results were obtained with ceftazidime followed by cefsulodin and piperacillin; 2) Pseudomonas bacterial counts dropped considerably half way through the treatment and more at the end with ceftazidime and cefsulodin; with the other antibiotics there was a drop followed by a new rise at the end; 3) there was no close correlation among clinical, radiological and bacterial scores; 4) few side-effects were observed: a rise in temperature on the 10th-12th day with piperacillin, transient vomiting with cefsulodin and diarrhoea with cefoperazone. Moderate sputum levels of antibiotics were observed in all sputum fractions with ceftazidime but no antibiotic was detected with axlocillin; variable results were obtained with cefoperazone.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/469/CN-00174469/frame.html>

### **See also**

DRUGS-EXP-CLIN-RES YR: 1983 VL: 98 DE: RCT NO: 9

### **Keywords**

Anti-Bacterial Agents; Azlocillin; Bacterial Infections; Cefoperazone; Cefotaxime; Cefsulodin; Ceftazidime; Infection; Moxalactam; pharmacological\_intervention; Piperacillin; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Penicillins; Cephalosporins;