primary studies - published RCT

Health care costs in a randomized trial of antimicrobial duration among cystic fibrosis patients with pulmonary exacerbations.

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

RCT. Parallel design. Single centre.

Participants

40 admitted with acute exacerbations of pulmonary symptoms associated with isolation of P. aeruginosa from sputum. 20 randomly allocated to each group. Aged 16 and over, diagnosed with CF and had grown P. aeruginosa consistently in their sputum for at least 6 months, were admitted to hospital with an exacerbation of pulmonary symptoms. All had chronic bronchopulmonary infection, malabsorption, and a sodi The P. aeruginosa isolated in sputum had to be sensitive to CPX, azlocillin and gentamicin. Excluded if had abnormal renal or hepatic function, previous adverse reactions to drugs in trial, were pregnant or taking theophyllines. Mean age: 23 years; range: 18 to 35 years. Country: UK. Sex: 11 males, 9 females in each group.

Interventions

Each treatment given 3 times a day for 10 days. Azlocillin (5g) plus gentamicin (80mg) both given intravenously or ciprofloxacin (500mg) given orally. Time-points when measurements were taken during the trial: day 1 (for all 40 participants), day 10 (for all 40 participants), 6 weeks (for 30 participants (15 in each group). On each of the 10 days of treatment temperature, max PEF and sputum weight were Time-points reported in the trial: day 1, day 10, 6 weeks.

Outcome measures

Sputum cultured and sensitivities for any isolates assessed by standard disc methods. Sputum weight PEF Any side-effects noted (gastro-intestinal, nervous system, other)*. CPX participants asked whether they preferred oral to IV treatment. Additional IV treatment required*. Isolation of antibiotic-resistant strains*. Death within 3 months post-treatment. Any treatment with IV anti-pseudomonal drugs within 3 months post-treatment*. FEV1* Blood and liver function tests. Temperature Scores on diary cards: breathing; sputum colour and volume; whether chest felt wheezy or better/same/worse as day 1*. FVC*

Main results

There was a significant improvement in lung function between days 1 and 10 in both groups (p less than 0.001). Significant improvement was maintained at 6 weeks after ciprofloxacin but not in the intravenous group. Improvement after ciprofloxacin was superior at day 10. Sputum weight decreased in both groups (p less than 0.001). Patient-recorded symptoms also improved in both groups. There was no serious toxicity or side-effects. Drug resistant organisms were isolated no more frequently after ciprofloxacin than after intravenous therapy. 17 of the ciprofloxacin-treated patients said they preferred oral treatment to intravenous therapy.

Authors' conclusions

Oral ciprofloxacin is a useful short-term treatment for patients with CF who are infected with Ps aeruginosa.

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See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Azlocillin; Bacterial Infections; Ciprofloxacin; Combined Modality Therapy; Gentamicin; Infection; Intravenous; Oral; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Exacerbation; Penicillins; Quinolones; Aminoglycosides;