

primary studies - published RCT

Feasibility and efficacy of combined pancreatic islet-lung transplantation in cystic fibrosis related diabetes -PIM study: a multicenter phase 1-2 trial.

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

Random allocation. Double-blinded. Placebo control. Parallel groups.

Participants

40 (20 males) participants. Age range 7 - 35 years. Chronic *P. aeruginosa* infection. Mean baseline FEV1 71% (SD 25) and 79% (SD 29) predicted in 2 treatment groups. Diagnostic criteria for CF not stated.

Interventions

Colistin (1 million units) or normal saline, twice daily for 3 months.

Outcome measures

Lung function (FEV1 and FVC), clinical score, sputum culture and sensitivity, blood tests (ESR, WCC).

Main results

Treatment with both ciprofloxacin and ofloxacin was associated with a good clinical response as judged by clinical score, lung function tests and inflammatory parameters; no difference between ciprofloxacin and ofloxacin was found. Adverse reactions were seen in nine of 24 patients who received ciprofloxacin and in six of 23 who received ofloxacin. The majority were dyspeptic reactions or photosensitivity. No serious adverse reactions occurred. Three cases of treatment failure were found, one of which was associated with development of resistant *P. aeruginosa* during ofloxacin treatment. The mean MIC of both drugs increased during treatment but returned to pretreatment values within three months.

Authors' conclusions

Ciprofloxacin and ofloxacin seem to be valuable agents for intermittent treatment of chronic *P. aeruginosa* lung infection in adult cystic fibrosis patients.

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See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Ciprofloxacin; Infection; Ofloxacin; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Colistin; Quinolones; other anti-bacterial agents;