primary studies - published RCT

The use of high resolution computerized tomography (HRCT) of the chest in evaluating the effect of tobramycin solution for inhalation in cystic fibrosis lung disease.

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

double-blind, placebo-controlled pilot study.

Participants

32 CF patients with mostly mild lung disease age > or = 6 years. Patients were chronically colonized with Pseudomonas aeruginosa for at least 6 months prior to and at enrollment. If patients were on TSI, they were taken off for at least 3 months prior to enrollment. Duration was 6 months; 31 subjects completed the study.

Interventions

Study medication was administered as 5 ml nebulized treatment twice a day for 28 days followed by 28 days off (one cycle). Study consisted of three cycles.

Outcome measures

HRCT and PFTs were evaluated at baseline, after 28 days of treatment and at the end of the study. Two radiologists scored all films using a validated system. A total HRCT score consists of the sum of subscores: linear opacities, hyperinflation, nodular opacities, peribronchial thickening, mucous plugging, and bronchiectasis; each subscore could range from 0 to 80, with potential total scores varying from 0 to 480. The percent of the maximum possible HRCT score was then calculated and used for all comparisons.

Main results

Using two tailed paired t-test, the percent maximum HRCT score decreased by 1.4 +/- 2.6% (mean +/- SD) (P = 0.049) and 0.3 +/- 2.8% (P = 0.63) for the TSI group and decreased by 0.1 +/- 1.5% (P = 0.74) and increased by 0.6 +/- 1.8% (P = 0.23) for the placebo group between visits 1 and 2, and visits 1 and 3, respectively. The data were then analyzed using a mixed model utilizing changes in scores over the durations of the study for each group. The change of HRCT score for the TSI group was -0.24/day (P = 0.02) and -0.03/day (P = 0.22), and for the control group the change was -0.01 (P = 0.93) and 0.02 (P = 0.29) between visits 1 and 2, and visits 1 and 3 respectively. FEF(25-75)% and FEV(1)% changes were not statistically significant using both analyses.

Authors' conclusions

HRCT seems to be more sensitive in detecting treatment effect than PFT in CF patients with mild lung disease, especially following the first treatment period (visit 2). Total HRCT score showed some improvement at the end of the study, though not statistically significant. This is probably due to obtaining the HRCT an average of 30 days after completion of the TSI treatment, and selection of study population with mostly mild lung disease. This could indicate that the most significant improvement in the total HRCT score in this patient population occurs after the first treatment period with TSI.

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See also

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Keywords

Anti-Bacterial Agents; Bacterial Infections; Bronchiectasis; Child; computed tomography; Infection; Inhalation OR nebulised; non pharmacological intervention - diagn; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; diagnostic procedures; Aminoglycosides;