primary studies - published RCT

High resolution computerized tomography of the chest and pulmonary function testing in evaluating the effect of tobramycin solution for inhalation in cystic fibrosis patients.

Code: PM17068818 **Year:** 2006 **Date:** 2006 **Author:** Nasr SZ

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

randomized, double-blind, placebo-controlled pilot study

Participants

32 subjects >/=6 years old with mild to moderate CF lung disease

Interventions

tobramycin solution for inhalation (TSI) for 28 days

Outcome measures

FEV1, FEF 25-75, HRCT scores

Main results

31 subjects completed the study.HRCT scores decreased 4.06 +/- 3.20 (mean +/- SD) for TSI and decreased 0.17 +/- 1.78 for placebo subjects (P = 0.13). Mean forced expiratory flow during middle half of forced vital capacity (FEF(25%-75%)) predicted increased 6.08 +/- 4.86 for TSI and decreased 0.60 +/- 2.34 for placebo (P = 0.23). Percentage forced expiratory volume in 1 s (FEV(1)) predicted increased slightly for both TSI and placebo (1.29 +/- 3.33 for TSI and 1.17 +/- 1.4 for placebo) (P = 0.97). Two of eight HRCT component scores (atelectasis and inhomogeneity) were observed to be highly discordant with observed HRCT global total score and other HRCT component scores. A modified total score was calculated by dropping them from the global total score. The modified HRCT total scores decreased 6.68 +/- 3.09 for TSI subjects and increased 0.02 +/- 2.0 for the placebo subjects (P = 0.07). Sample sizes were calculated to show statistical significance by differences in modified total HRCT scores, global total HRCT scores, FEF(25%-75%) predicted or FEV(1) % predicted. A total of 60, 100, 200, and over 800 patients would be necessary respectively.

Authors' conclusions

HRCT can be a useful measure of change in CF pulmonary disease, requiring a smaller sample size than that required to show treatment effect by pulmonary function testing (PFT) alone.

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See also

Pediatr Pulmonol. 2006 Dec;41(12):1129-37.

Keywords

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