

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.

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

randomized, double-blind, placebo-controlled pilot study

### Participants

32 subjects  $\geq 6$  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  $4.06 \pm 3.20$  (mean  $\pm$  SD) for TSI and decreased  $0.17 \pm 1.78$  for placebo subjects ( $P = 0.13$ ). Mean forced expiratory flow during middle half of forced vital capacity (FEF(25%-75%)) predicted increased  $6.08 \pm 4.86$  for TSI and decreased  $0.60 \pm 2.34$  for placebo ( $P = 0.23$ ). Percentage forced expiratory volume in 1 s (FEV(1)) predicted increased slightly for both TSI and placebo ( $1.29 \pm 3.33$  for TSI and  $1.17 \pm 1.4$  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  $6.68 \pm 3.09$  for TSI subjects and increased  $0.02 \pm 2.0$  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;