

primary studies - published RCT

Long term azithromycin in children with cystic fibrosis: a randomised, placebo-controlled crossover trial.

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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 \pm 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.

[http://dx.doi.org/10.1016/S0140-6736\(02\)11081-6](http://dx.doi.org/10.1016/S0140-6736(02)11081-6)

See also

Lancet. 2002 Sep 28;360(9338):978-84.

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;