

primary studies - published RCT

Recombinant human DNase nebulisation in children with cystic fibrosis: before bedtime or after waking up?.

Code: PM17596273

Year: 2007 Date: 2011

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

The Australasian Cystic Fibrosis Bronchoalveolar Lavage (ACFBAL) randomized controlled trial

Participants

infants diagnosed with cystic fibrosis through newborn screening programs in 8 Australasian cystic fibrosis centers. Recruitment occurred between June 1, 1999, and April 30, 2005, with the study ending on December 31, 2009. Of 267 infants diagnosed with cystic fibrosis following newborn screening, 170 were enrolled and randomized, and 157 completed the study.

Interventions

BAL-directed (n = 84) or standard (n = 86) therapy until age 5 years. The BAL-directed therapy group underwent BAL before age 6 months when well, when hospitalized for pulmonary exacerbations, if *Pseudomonas aeruginosa* was detected in oropharyngeal specimens, and after *P. aeruginosa* eradication therapy. Treatment was prescribed according to BAL or oropharyngeal culture results

Outcome measures

Primary outcomes at age 5 years were prevalence of *P. aeruginosa* on BAL cultures and total cystic fibrosis computed tomography (CF-CT) score (as a percentage of the maximum score) on high-resolution chest CT scan.

Main results

At age 5 years, 8 of 79 children (10%) in the BAL-directed therapy group and 9 of 76 (12%) in the standard therapy group had *P. aeruginosa* in final BAL cultures (risk difference, -1.7% [95% confidence interval, -11.6% to 8.1%]; P = .73). Mean total CF-CT scores for the BAL-directed therapy and standard therapy groups were 3.0% and 2.8%, respectively (mean difference, 0.19% [95% confidence interval, -0.94% to 1.33%]; P = .74).

Authors' conclusions

Among infants diagnosed with cystic fibrosis, BAL-directed therapy did not result in a lower prevalence of *P. aeruginosa* infection or lower total CF-CT score when compared with standard therapy at age 5 years.

<http://dx.doi.org/10.1183/09031936.00031107>

See also

Eur Respir J. 2007 Oct;30(4):763-8. Epub 2007 Jun 27.

Keywords

BAL; Anti-Bacterial Agents; *Pseudomonas aeruginosa*; *Pseudomonas*; Bacterial Infections; Infection; pharmacological_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; Bronchoalveolar Lavage; Infant; Newborn; Child; Biomarker; non pharmacological intervention - diagn; Exacerbation; diagnostic procedures;