primary studies - published RCT

Experience using centralized spirometry in the phase 2 randomized, placebo-controlled, double-blind trial of denufosol in patients with mild to moderate cystic fibrosis.

Code: PM17728193 **Year:** 2008 **Date:** 2008 **Author:** Goss CH

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

phase 2 randomized, placebo-controlled, double-blind clinical trial of denufosol in patients with mild to moderate CF

Participants

n=89; spirometries=1418

Interventions

spirometry

Outcome measures

Uniform spirometers were used with electronic data transmission of all the data to a reading center. Spirometry was evaluated for quality by a central reader based on start of test, cough during the test, and evidence of a plateau.

Main results

In only 5 instances did the central reading center need to give feedback to sites regarding the quality of spirometry. The study site data matched the central reading center's data for all but 78 (6%) spirometry values in 33 patients. Many of these differences were small with only 35 (3%) values differing by more than 50 mL in 26 patients.

Authors' conclusions

Spirometry in this clinical trial was of high quality with low rate of significant centralized over-read.

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See also

J Cyst Fibros. 2008 Mar;7(2):147-53. Epub 2007 Aug 28.

Keywords

Adolescent; Other drugs; denufosol; Inhalation OR nebulised; pharmacological_intervention; placebo;