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:** 2012 **Author:** Goss CH

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

Prospective, centrally randomised, phase III, open-label study

Participants

Patients with cystic fibrosis (CF) aged â‰¥6 years with chronic Pseudomonas aeruginosa lung infection

Interventions

Patients were randomised to Colobreathe dry powder for inhalation (CDPI, one capsule containing colistimethate sodium 1 662 500 IU, twice daily) or three 28-day cycles with twice-daily 300 mg/5 ml tobramycin inhaler solution (TIS). Study duration was 24 weeks.

Outcome measures

FEV1% predicted at week 24; proportion of colistin-resistant isolates; number of adverse events.

Main results

380 patients were randomised. After logarithmic transformation of data due to a non-normal distribution, adjusted mean difference between treatment groups (CDPI vs TIS) in change in forced expiratory volume in 1 s (FEV1% predicted) at week 24 was âˆ'0.97% (95% CI âˆ'2.74% to 0.86%) in the intention-to treat population (n=374) and âˆ'0.56% (95% CI âˆ'2.71% to 1.70%) in the per protocol population (n=261). The proportion of colistin-resistant isolates in both groups was â‰¤1.1%. The number of adverse events was similar in both groups. Significantly more patients receiving CDPI rated their device as â€˜very easy or easy to useâ€™ (90.7% vs 53.9% respectively; p

Authors' conclusions

CDPI demonstrated efficacy by virtue of non-inferiority to TIS in lung function after 24 weeks of treatment. There was no emergence of resistance of P aeruginosa to colistin. Overall, CDPI was well tolerated.

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See also

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

Keywords

Anti-Bacterial Agents; Bacterial Infections; colistimethate; Colistin; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Powders; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; other anti-bacterial agents;