primary studies - published RCT

Safety, efficacy and convenience of colistimethate sodium dry powder for inhalation (Colobreathe DPI) in patients with cystic fibrosis: a randomised study.

Code: PM23135343 **Year:** 2013 **Date:** 2013 **Author:** Schuster A

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

AB - PURPOSE: To assess efficacy and safety of a new dry powder formulation of inhaled colistimethate sodium in patients with cystic fibrosis (CF) aged >/=6 years with chronic Pseudomonas aeruginosa lung infection. STUDY DESIGN AND METHODS: A prospective, centrally randomised, phase III, open-label study in patients with stable CF aged >/=6 years with chronic P aeruginosa lung infection. 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. 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 -0.98% (95% CI -2.74% to 0.86%) in the intention-to-treat population (n=373) and -0.56% (95% CI -2.71% to 1.70%) in the per protocol population (n=261). The proportion of colistin-resistant isolates in both groups was

Participants

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Interventions

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Outcome measures

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Main results

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Authors' conclusions

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See also

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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;