

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.**

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**Author:** Schuster A

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

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

### **Participants**

Patients with cystic fibrosis (CF) aged  $\geq 6$  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  $-0.97\%$  (95% CI  $-2.74\%$  to  $0.86\%$ ) in the intention-to treat population ( $n=374$ ) 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  $\approx 1.1\%$ . The number of adverse events was similar in both groups. Significantly more patients receiving CDPI rated their device as 'very easy or easy to use' (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**

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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;