

Other Reviews - - Other Review

The effect of discontinuing hypertonic saline or dornase alfa on mucociliary clearance in elexacaftor/tezacaftor/ivacaftor treated people with cystic fibrosis: The SIMPLIFY-MCC Study.

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Author: Donaldson SH

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

HTA report

Participants

CF patients with *Pseudomonas aeruginosa* lung infection in CF.

Interventions

Colistimethate sodium dry powder for inhalation (DPI) (Colobreathe®), Forest Laboratories) and tobramycin DPI (TOBI Podhaler®), Novartis Pharmaceuticals)

Outcome measures

Forced expiratory volume in first second percentage predicted (FEV1%). Quality-adjusted life-years (QALYs). Cost-effectiveness ratio

Main results

Three randomised controlled trials (RCTs) were included in the clinical effectiveness review. Both colistimethate sodium DPI and tobramycin DPI were reported to be non-inferior to nebulised tobramycin for the outcome forced expiratory volume in first second percentage predicted (FEV1%). It was not possible to draw any firm conclusions as to the relative efficacy of colistimethate sodium DPI compared with tobramycin DPI. The economic analysis suggests that colistimethate sodium DPI produces fewer quality-adjusted life-years (QALYs) than nebulised tobramycin. Given the incremental discounted lifetime cost of tobramycin DPI compared with nebulised tobramycin, it highly unlikely that tobramycin DPI has an incremental cost-effectiveness ratio that is better than £30,000 per QALY gained. LIMITATION: The uncertainty surrounding the short-term evidence base inevitably results in uncertainty surrounding the long-term clinical effectiveness and cost-effectiveness of colistimethate sodium DPI.

Authors' conclusions

Both DPI formulations have been shown to be non-inferior to nebulised tobramycin as measured by FEV1%. The results of these trials should be interpreted with caution owing to the means by which the results were analysed, the length of follow-up, and concerns about the ability of FEV1% to accurately represent changes in lung health. Although the increase in QALYs is expected to be lower with colistimethate sodium DPI than with nebulised tobramycin, a price for this intervention had not been agreed at the time of the assessment. Depending on the price of colistimethate sodium DPI, this results either in a situation whereby colistimethate sodium DPI is dominated by nebulised tobramycin or in one whereby the incremental cost-effectiveness of nebulised tobramycin compared with colistimethate sodium DPI is in the range of £24,000-277,000 per QALY gained. The economic analysis also suggests that, given its price, it is unlikely that tobramycin DPI has a cost-effectiveness ratio of

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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; Tobramycin; Aminoglycosides;