HTA - - Health Technology Assessment Report

The effect of azithromycin on structural lung disease in infants with cystic fibrosis (COMBAT CF): a phase 3, randomised, double-blind, placebo-controlled clinical trial.

Code: PM35662406 **Year:** 2022 **Date:** 15 Jun 2011 **Author:** Stick SM

List of included studies (3)

Davies 2004; Konstan 2011 (Tobramicin); Forest trial 2011 (ongoing?)

Participants

CF patients with Pseudomonas aeruginosa lung infection

Interventions

colistimethate sodium and tobramycin powder for inhalation

Outcome measures

Lung function, microbial response, respiratory symptoms and the frequency/severity of acute exacerbations; adverse event profile; cost-effectiveness

Main results

Both DPI formulations have been shown to be non-inferior to nebulised tobramycin as measured by FEV1%. However, the results of these trials should be interpreted with caution due 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. The impact of resistance to tobramycin is not known. When considered alongside other outcomes, it would appear possible that when compared to nebulised treatment, patients on DPI formulations, but less time on antibiotics, more cough adverse events and may be more likely to not tolerate the treatment. As such, based on the clinical evidence, the advantages and non-inferiority of DPI treatments compared to nebulised tobramycin remain unclear when all relevant outcomes are considered. Inevitably, the cost-effectiveness of the dry powder formulations is subject to considerable uncertainty. The Assessment Group model suggests that colistimethate sodium is expected to produce fewer QALYs than nebulised tobramycin. Depending on the price adopted for colistimethate sodium DPI, this results either in a situation whereby colistimethate sodium DPI is dominated by nebulised tobramycin, or one whereby the incremental cost-effectiveness of nebulised tobramycin versus colistimethate sodium DPI is in the range £ 24,000 to £ 277,000 per QALY gained (South - West quadrant). The economic analysis also suggests that given its price, it is highly unlikely that tobramycin DPI has an incremental cost-effectiv eness ratio below £30,000 per QALY gained when compared against nebulised tobramycin.

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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;