primary studies - published RCT

The clinical and microbiological utility of inhaled aztreonam lysine for the treatment of acute pulmonary exacerbations of cystic fibrosis: An open-label randomised crossover study (AZTEC-CF).

Code: PM33358119 **Year:** 2021 **Date:** **Author:** Frost F

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

Open-label randomised crossover pilot trial

Participants

16 adults with CF and P. aeruginosa infection. Median [IQR] age was 29.5 [24.5-32.5], mean ± SD forced expiratory volume in 1 second (FEV1) was 52.4 ± 14.7 % predicted.

Interventions

Participants were randomised to sequentially receive 14 days of inhaled aztreonam lysine plus IV colistimethate (AZLI+IV), or dual IV antibiotics (IV+IV).

Outcome measures

Primary outcome was absolute change in % predicted FEV1. Other outcomes evaluated changes in quality of life, bacterial load and the lung microbiota.

Main results

The difference between mean change in lung function at day 14 between AZLI+IV and IV+IV was +4.6% (95% CI 2.1-7.2, p=0.002). The minimum clinically important difference of the Cystic Fibrosis Revised Questionnaire (CFQ-R) was achieved more frequently with AZLI+IV (10/12, 83.3%) than IV+IV (7/16, 43.8%), p=0.05. No differences were observed for modulation of serum white cell count, C-reactive protein or sputum bacterial load. Microbiome compositional changes were observed with IV+IV (Bray-Curtis r(2)=0.14, p=0.02), but not AZLI+IV (r(2)=0.03, p=0.64).

Authors' conclusions

In adults with CF and P. aeruginosa infection experiencing an acute pulmonary exacerbation, AZLI+IV improved lung function and quality of life compared to the current standard treatment. These findings support the need for larger definitive trials of inhaled antibiotics in the acute setting.

http://dx.doi.org/10.1016/j.jcf.2020.12.012

See also

J Cyst Fibros. 2021 Nov;20(6):994-1002. doi: 10.1016/j.jcf.2020.12.012. Epub 2021 Jan 7.

Keywords

Anti-Bacterial Agents; Aztreonam; Bacterial Infections; Colonization; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Monobactams; Powders; Tobramycin; Aminoglycosides; Exacerbation;