primary studies - published RCT

Long-term amikacin liposome inhalation suspension in cystic fibrosis patients with chronic P. aeruginosa infection.

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

Extension of a phase 3, randomised, open-label study

Participants

Patients with cystic fibrosis (CF) and chronic Pseudomonas aeruginosa infection

Interventions

In CLEAR-108-a phase 3, randomised, open-label study-once-daily amikacin liposome inhalation suspension (ALIS) was noninferior to twice-daily tobramycin inhalation solution (TIS) in improving lung function in patients with cystic fibrosis (CF) and chronic Pseudomonas aeruginosa infection after 3 treatment cycles (28 days on/28 days off). The CLEAR-110 extension study assessed long-term safety, tolerability, and efficacy of ALIS in eligible patients who completed CLEAR-108. Patients received once-daily ALIS 590 mg for 12 treatment cycles (96 weeks). Patients were grouped by prior treatment: the "prior-ALIS" cohort received ALIS in CLEAR-108, and the "ALIS-naive" cohort received TIS in CLEAR-108.

Outcome measures

Long-term safety, tolerability, and efficacy of ALIS

Main results

206 patients (prior-ALIS, n=92; ALIS-naive, n=114) entered CLEAR-110 and received â‰¥1 dose of ALIS. Most patients (88.8%) experienced â‰¥1 treatment-emergent adverse event (TEAE) through day 672 (end of year 2). Most TEAEs (72.3%) were mild or moderate in severity. Severe TEAEs were reported in 31 patients (15.0%). Two life-threatening TEAEs (haemoptysis; intestinal obstruction) and 1 death (cardiac failure) were reported. Twenty-one patients (10.2%) discontinued treatment due to a TEAE (mostly infective pulmonary exacerbation of CF). Mean change from baseline in forced expiratory volume in 1 second percent predicted at day 672 was -3.1% (prior-ALIS, -4.0%; ALIS-naive, -2.3%). Mean change from baseline in sputum density of P. aeruginosa at day 672 was 0.02 (prior-ALIS, -0.16; ALIS-naive, 0.19) log CFU/g.

Authors' conclusions

Long-term treatment with ALIS was well tolerated with a favourable adverse event profile and demonstrated continued antibacterial activity in CF patients with chronic P. aeruginosa infection.

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See also

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Keywords

Amikacin; Anti-Bacterial Agents; arikace; Liposomal amikacin; Bacterial Infections; Infection; Inhalation OR nebulised; pharmacological_intervention; placebo; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Aminoglycosides; Liposomal Amikacin;