

primary studies - published RCT

Amikacin liposome inhalation suspension for chronic *Pseudomonas aeruginosa* infection in cystic fibrosis.

Code: PM31451351

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

RCT

Participants

Patients with CF and forced expiratory volume in 1 s (FEV₁) \geq 25% of predicted value at screening and CF with chronic *P. aeruginosa*

Interventions

Patients were randomly assigned to receive 3 treatment cycles (28 days on, 28 days off) of amikacin liposome inhalation suspension (ALIS, 590 mg QD) or tobramycin inhalation solution (TIS, 300 mg BID).

Outcome measures

The primary endpoint was noninferiority of ALIS vs TIS in change from baseline to day 168 in FEV₁ (per-protocol population). Secondary endpoints included change in respiratory symptoms by Cystic Fibrosis Questionnaire-Revised (CFQ-R).

Main results

The study was conducted February 2012 to September 2013. ALIS was noninferior to TIS (95% CI, -4.95 to 2.34) for relative change in FEV₁ (L) from baseline. The mean increases in CFQ-R score from baseline on the Respiratory Symptoms scale suggested clinically meaningful improvement in both arms at the end of treatment in cycle 1 and in the ALIS arm at the end of treatment in cycles 2 and 3; however, the changes were not statistically significant between the 2 treatment arms. Treatment-emergent adverse events (TEAEs) were reported in most patients (ALIS, 84.5%; TIS, 78.8%). Serious TEAEs occurred in 17.6% and 19.9% of patients, respectively; most were hospitalisations for infective pulmonary exacerbation of CF.

Authors' conclusions

Cyclical dosing of once-daily ALIS was noninferior to cyclical twice-daily TIS in improving lung function.

<http://dx.doi.org/10.1016/j.jcf.2019.08.001>

See also

J Cyst Fibros. 2020 Mar;19(2):284-291. doi: 10.1016/j.jcf.2019.08.001. Epub 2019 Aug 23.

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;