primary studies - published RCT

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

Code: PM31451351 **Year:** 2020 **Date:** 2020 **Author:** Bilton D

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

RCT

Participants

Patients with CF and forced expiratory volume in 1â€¯s (FEV(1)) â‰¥25% of predicted value at screening and CF with chronic P. aeruginosa

Interventions

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

Outcome measures

The primary endpoint was noninferiority of ALIS vs TIS in change from baseline to day 168 in FEV(1) (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 FEV(1) (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;