

primary studies - published RCT

Inhaled aztreonam for chronic Burkholderia infection in cystic fibrosis: A placebo-controlled trial.

Code: PM24176390

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

Phase 2a randomized, double-blind, placebo-controlled study

Participants

30 adult CF patients.

Interventions

100 or 200mg of inhaled Alpha-1 HC once daily for 3 weeks; subjects were randomized in a 2:1 ratio to receive Alpha-1 HC or placebo.

Outcome measures

Safety

Main results

Drug delivery was confirmed by a dose-dependent increase in the sputum alpha1-PI. Seven (20.0%) of the 35 adverse events in the 100-mg dose group, 3 (13.0%) of 23 in the 200-mg dose group, and 4 (14.3%) of 28 in the placebo group were drug-related in these subjects. One serious adverse event occurred in 1 subject within each group.

Authors' conclusions

Alpha-1 HC inhalation was safe and well tolerated.

[http://www.cysticfibrosisjournal.com/article/S1569-1993\(13\)00148-3/fulltext](http://www.cysticfibrosisjournal.com/article/S1569-1993(13)00148-3/fulltext)

See also

J Cyst Fibros. 2013 Oct 28. pii: S1569-1993(13)00148-3. doi: 10.1016/j.jcf.2013.08.011.

Keywords

Infection; Inhalation OR nebulised; pharmacological_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; alpha1-anti-trypsin; Anti-Inflammatory Agents; Anti-Inflammatory Agents - excl Steroids; Alpha1-Proteinase Inhibitor;