primary studies - published RCT

Inhaled alpha1-proteinase inhibitor therapy in patients with cystic fibrosis.

Code: PM26321218 **Year:** 2016 **Date:** 2016 **Author:** Gaggar A

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://dx.doi.org/10.1016/j.jcf.2015.07.009

See also

J Cyst Fibros. 2016 Mar;15(2):227-33. doi: 10.1016/j.jcf.2015.07.009. Epub 2015 Aug 28.

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;