

primary studies - published RCT

A Randomized Trial of Antimicrobial Duration for Cystic Fibrosis Pulmonary Exacerbation Treatment.

Code: PM34469706 Year: 2021 Date: 2021

Author: Goss CH

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

Multi-center, randomized, controlled, clinical trial

Participants

Adults with CF with pulmonary exacerbation

Interventions

Treatment with intravenous antimicrobials. After 7-10-days of treatment, participants exhibiting pre-defined lung function and symptom improvements were randomized to 10- or 14-days total antimicrobial duration; all others were randomized to 14- or 21-days.

Outcome measures

The primary outcome was percent predicted forced expiratory volume in 1 second (ppFEV1) change from treatment initiation to two weeks after cessation. Among early responders non-inferiority of 10-days to 14-days was tested; superiority of 21-days compared to 14-days was compared for the others. Symptoms, weight, and adverse events were secondary.

Main results

Among 982 randomized, 277 met improvement criteria and were randomized to 10- or 14-days treatment; the remaining 705 received 21- or 14-days. Mean ppFEV1 change was 12.8 and 13.4 for 10- and 14-days, respectively, a $\hat{a}\in$ 0.65 difference [95%Cl $\hat{a}\in$ 3.3, 2.0], excluding the pre-defined noninferiority margin. The 21- and 14-day arms experienced 3.3 and 3.4 mean ppFEV1 changes, a difference of $\hat{a}\in$ 0.10 [$\hat{a}\in$ 1.3, 1.1]. Secondary endpoints and sensitivity analyses were supportive.

Authors' conclusions

Among CF adults with early treatment improvement during exacerbation, ppFEV1 after 10-days of intravenous antimicrobials is not inferior to 14-days. For those with less improvement after one week, 21-days is not superior to 14-days.

http://dx.doi.org/10.1164/rccm.202102-0461OC

See also

Am J Respir Crit Care Med. 2021 Sep 1. doi: 10.1164/rccm.202102-0461OC.

Keywords

Anti-Bacterial Agents; Bacterial Infections; Drug Administration Schedule; Infection; Intravenous; pharmacological_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; Exacerbation;