primary studies - published RCT

A randomized controlled trial to evaluate the lung clearance index as an outcome measure for early phase studies in patients with cystic fibrosis.

Code: PM26856191 **Year:** 2016 **Date:** 2021 **Author:** Amin R

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 â€'0.65 difference [95%CI â€'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 â€'0.10 [â€'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.

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See also

Respir Med. 2016 Feb 2. pii: S0954-6111(16)30016-6. doi: 10.1016/j.rmed.2016.01.020.

Keywords

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