primary studies - published RCT

Study design considerations for the Standardized Treatment of Pulmonary Exacerbations 2 (STOP2): A trial to compare intravenous antibiotic treatment durations in CF.

Code: PM29170074 **Year:** 2018 **Date:** 2018 **Author:** Heltshe SL

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

Multicenter, randomized, prospective study

Participants

People with CF and their caregivers.

Interventions

Study comparing the efficacy and safety of different durations of IV antibiotics for Pulmonary exacerbations (PEx)

Outcome measures

Forced expiratory volume in 1s (FEV1% predicted) and symptom responses at 7-10days

Main results

IV antibiotic duration was cited as the most important PEx research question by responding CF physicians and top concern among surveyed CF patients/caregivers. During PEx, forced expiratory volume in 1s (FEV1% predicted) and symptom responses at 7-10days of IV antibiotics identified two distinct groups: early robust responders (ERR) who subsequently experienced greater FEV1 improvements compared to non-ERR (NERR). In addition to greater FEV1 and symptom responses, only 14% of ERR patients were treated with IV antibiotics for >15days, compared with 45% of NERR patients.

Authors' conclusions

A divergent trial design that evaluates subjects' interim improvement in FEV1 and symptoms to tailor randomization to IV treatment duration (10 vs. 14days for ERR, 14 vs. 21days for NERR) may alleviate physician and patient concerns about excess or inadequate treatment. Such a study has the potential to provide evidence necessary to standardize IV antibiotic duration in CF PEx care -a first step to conducting PEx research of other treatment features.

http://dx.doi.org/10.1016/j.cct.2017.11.012

See also

Contemp Clin Trials. 2018 Jan;64:35-40. doi: 10.1016/j.cct.2017.11.012. Epub 2017 Nov 21.

Keywords

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