Early Pseudomonas Infection Control (EPIC) (EPIC-001)

Summary

This study evaluated different treatment strategies for eradication of Pseudomonas aeruginosa in CF people with a new infection. One strategy was to treat participants with antibiotics only when Pseudomonas aeruginosa was isolated from respiratory cultures taken throughout the study (culture-based). A second strategy was to have participants take antibiotics regularly - every three months (cycled) over the 18 months of the study. In addition, within each strategy (culture-based or cycled) the antibiotics that were given included inhaled tobramycin either given with or without oral ciprofloxacin. Participants were randomized to one of these four treatment approaches.

Specimen Information

Status: Specimens are Available

The primary purpose of this study was to evaluate 4 different treatment regimens to eradicate P. aeruginosa infection. The four treatment regimens included TOBI and ciprofloxacin (or placebo) TOBI was either dosed in a cyclical fashion (1 month on-drug followed by 2 months off-drug) for 18 months, or only dosed (1 month on-drug) when OP or sputum cultures were positive for P. aeruginosa. Serum specimens were collected at baseline and at 3 additional timepoints over the next 18 months. Any P aeruginosa isolated was shipped to Seattle Children's for Banking.

Visit #	Time From Baseline	Specimens Collected
1	+0 Days	PA isolates, Serum
4	+22 Weeks	PA isolates, Serum
6	+46 Weeks	PA isolates, Serum
8	+70 Weeks	PA isolates, Serum

Study Design

Study Type?	Interventional
Randomized Study?	Yes
Placebo Controlled?	Yes
Length of Participation	18 Months
Number of Study Visits?	8

Additional Information

Phase?	Phase Three
Study Sponsor?	Ramsey, Bonnie
Study Drugs?	TOBI

Eligibility

Age	1 Years to 12 Years
Mutation(s)	No Mutation Requirement
FEV1% Predicated	No FEV1 Limit
PA Status	Positive
Other	To be eligible for this study, subjects must have early P. aeruginosa infection, defined as first isolation within 6 months prior to baseline or new isolation after at least a 2 year time frame with negative cultures.

Study Results

WHAT WE LEARNED:

Study results show that there was no significant difference in the rate of pulmonary exacerbations between the treatment groups. Additionally, the frequency of adverse events was similar across groups.

PRIMARY FINDINGS:

EFFECTIVENESS:

This study was conducted between December 2004 and July 2009. A total of 304 participants were randomized to one of the four treatment group and most participants completed the study (between three and eight participants withdrew in the 4 treatment groups). The primary objective was to investigate if cycled antimicrobial treatment (with or without ciprofloxacin) reduced the time to first pulmonary exacerbation requiring intravenous antibiotics or hospital admission compared to culture-based therapy. There were no differences in the exacerbation rates between cycled and culture-based groups or between inhaled tobramycin with ciprofloxacin vs. inhaled tobramycin without ciprofloxacin.

SAFETY:

Adverse events were similar across groups although respiratory events were more common in the groups assigned to receive oral ciprofloxacin.

CITATION:

Arch Pediatr Adolesc Med 2011,165(9):847-856, J Cyst Fibros 2012,DOI doi.org/10.1016/j.jcf.2012.08., J Ped Infect Dis 2014,3(2), Pediatr Pulmonol 2013,48(10):943-953

For more information about the results of this study and where it was conducted, visit ClinicalTrials.gov.