

CFFT Specimen Banking			
Study Long Title	Effectiveness and Safety of Intermittent Antimicrobial Therapy for the Treatment of New Onset Pseudomonas aeruginosa Airway Infection in Young Patients with Cystic Fibrosis		
Short Name	EPIC Clinical		
Specimens Currently Available to Other Researchers	Yes		
Current Study Status	Closed		
Study Timeline Metrics			
	Planned	Actual (Sponsor)	
Begin Enrollment		12/20/2004	
Complete Enrollment	02/15/2008	02/12/2008	
Study Complete	06/30/2009	07/15/2009	
Number of Patients Planned	305		
General Study Information			
Study Type	Interventional		
Intervention Type	Anti-Infective		
Study Drug (Primary)	TOBI		
Study Drug (Non-Primary)	Ciprofloxacin (oral)		
Control Type	Placebo		
Blinded	Yes		
Randomized	Yes		
Duration of Subject Participation	18 Months		
Endpoints Evaluated	Spirometry, Exacerbations, LRT Microbiology, Growth		
Trial Specific Link on ClinicalTrials.gov	http://clinicaltrials.gov/ct2/show/NCT00097773?term=epic+clinical+and+cf&rank=1		
Primary Manuscript Link	http://archpedi.ama-assn.org/cgi/reprint/165/9/847		
Primary Manuscript Citation	Arch Pediatr Adolesc Med 2011;165(9):847-856		
Eligibility Criteria			
Age	1 Years to 12 Years		
FEV1	No FEV1 requirement		
P. aeruginosa status	Positive		
B. cepacia status	Not Applicable		
Other Primary Eligibility Requirements			
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.			
Biorepository Specimen Information			
General Specimen Information			
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	serum, PA isolates	
4	+22 Weeks	serum, PA isolates	
6	+46 Weeks	serum, PA isolates	
8	+70 Weeks	serum, PA isolates	