

STOP 2: Treatment of pulmonary exacerbations in people with CF (STOP2-IP-15)

Summary

This study is taking place at multiple care centers across the U.S. It will look at the safety and effectiveness of different lengths of IV treatment for pulmonary exacerbations in people with CF.

Pulmonary exacerbations are treated with varying antibiotics for varying time periods based on individual needs determined by patients, their families and care providers. This study will look at the safety and effectiveness of three different lengths of IV antibiotic treatment for pulmonary exacerbations. Participants who respond early to IV treatment will receive antibiotics for 10 or 14 days. Those who do not respond early will receive antibiotics for 14 or 21 days. Researchers will study the effectiveness of different IV treatment lengths by measuring changes in lung function.

This study is for people with CF who experience a pulmonary exacerbation and are planning to receive IV antibiotic treatment. This study may require lung function tests and/or other measurements.

Specimen Information

Status: Specimens are Available

For each subject enrolled in this study a specimen for banking is collected on Day 1 baseline (subject has been diagnosed with a pulmonary exacerbation and has been started on IV antibiotics). A second sample is collected between Days 7 to 10 (during antibiotic treatment) and a third sample is collected 2-weeks after antibiotic treatment has been concluded (variable timing depending on which treatment arm the subject was randomized to).

Visit #	Time From Baseline	Specimens Collected
1	+0 Days	Serum
2	+7 Days	Serum
3	+25 Days	Serum

Study Design

Study Type?	Interventional
Randomized Study?	Yes
Placebo Controlled?	No
Length of Participation	35 Days

Number of Study Visits? 3

 **Additional Information**

Phase? Not Applicable
Study Sponsor? Flume, Patrick
Study Drugs? Multiple systemic antibiotics

 **Eligibility**

Age 18 Years and Older
Mutation(s) No Mutation Requirement
FEV1% Predicated No FEV1 Limit
PA Status Not Applicable
Other

Study Results

STUDY RESULTS NOT YET AVAILABLE

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