Biomarkers of Pulmonary Exacerbation in Patients with CF (SAGEL07A0)

Summary

This study was conducted to identify if there are biomarkers in the blood of people with CF experiencing a pulmonary exacerbation that change (increase or decrease) in response to the treatments for the exacerbation. A biomarker is a substance (biochemical) in the body that can be used to measure disease activity or the effects of treatment. There is a need to identify biomarkers in CF that can be used to more quickly evaluate potential new treatments. Pulmonary exacerbations provide a good opportunity to define the effect of intravenous antibiotics on specific biomarkers and to determine whether clinical improvements seen as a result of treatment are reflected in changes to these bloodstream biomarkers.

Specimen Information

Status: Specimens are Available

Baseline samples were taken from subjects who are having a new pulmonary exacerbation based on Rosenfeld score and within 24 hours of initiation of IV antibiotic therapy. A second sample was collected after 10 to 14 days of antibiotic treatment. Additional samples were collected at least 2 weeks after completing systemic antibiotics and then annually for the next 2 years.

Visit #	Time From Baseline	Specimens Collected
1	+0 Days	EDTA plasma
2	+14 Days	EDTA plasma
3	+28 Days	EDTA plasma
4	+1 Years	EDTA plasma
5	+2 Years	EDTA plasma

Study Design

Study Type? Interventional
Randomized Study? No
Placebo Controlled? No
Length of Participation 14 Days
Number of Study Visits? 2

Additional Information

Phase? Not Applicable

Study Sponsor?	Sagel, Scott
Study Drugs?	Multiple systemic antibiotics

Eligibility

Age	10 Years and Older
Mutation(s)	No Mutation Requirement
FEV1% Predicated	No FEV1 Limit
PA Status	Not Applicable
Other	Additional key eligibility criteria: Initiation of IV antibioic therapy for a clinially diagnosed acute pulomonary exacerbation.

Study Results

WHAT WE LEARNED:

Study results show that there was a significant reduction in ten different plasma proteins during antibiotic treatment for pulmonary exacerbations. Certain proteins were strongly correlated with improvements in lung function after treatment.

PRIMARY FINDINGS:

EFFECTIVENESS:

This study was conducted between December 2007 and July 2012. Of the 123 participants who enrolled, 103 had paired blood samples (samples taken before and after antibiotic treatment for a pulmonary exacerbation). This measured changes in 15 plasma proteins after intravenous antibiotic treatment for pulmonary exacerbations. The objective was to determine if any plasma inflammatory proteins can predict a clinical response to antibiotic therapy. Significant reductions in ten plasma proteins were observed after antibiotic treatment. At the start of the exacerbation, plasma C-reactive protein (CRP), serum amyloid A (SAA), calprotectin, and neutrophil elastase antiprotease complexes (NEAPC) correlated most strongly with clinical measures. Reductions in CRP, SAA, IL-1ra, and haptoglobin were most associated with improvements in lung function after antibiotic therapy.

SAFETY:

Not applicable

CITATION:

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