Phase 2 study of oral glutathione in children with cystic fibrosis (GROW-IP-16)

Summary

This study is taking place at multiple care centers across the U.S. It will look at the safety and effectiveness of the oral drug glutathione in children with cystic fibrosis. This study is placebo-controlled, meaning that some participants will receive oral glutathione, and others will receive a placebo. Researchers will test the effect of oral glutathione by measuring growth (Z-scores) in addition to other measures. This study is for children between the ages of 2 and 11 who use pancreatic enzyme replacement therapy (PERT) and are clinically stable. This study may require blood draws, stool samples or other measurements.

Specimen Information

Status: Specimens are Available

The purpose of this randomized, placebo-controlled study is to evaluate the effects of oral glutathione on growth in children with CF. Plasma and stool are being banked for this study.

Visit #	Time From Baseline	Specimens Collected
2	+0 Days	EDTA plasma, Stool
3	+12 Weeks	Stool
4	+24 Weeks	EDTA plasma, Stool

Study Design

Study Type? Interventional
Randomized Study? Yes
Placebo Controlled? Yes
Length of Participation 6 Months
Number of Study Visits? 4

Additional Information

Phase? Phase Two
Study Sponsor? Schwarzenberg, Sarah
Study Drugs? Glutathione

Eligibility

Age	24 Months to 10 Years
Mutation(s)	No Mutation Requirement
FEV1% Predicated	No FEV1 Limit
PA Status	Not Applicable
Other	Participants must have a weight-for-age between the 10th and 50th percentiles at screening.

Study Results

STUDY RESULTS NOT YET AVAILABLE

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