

| CF Foundation Specimen Banking | | | |
|--|---|---------------------|--|
| Study Long Title | A Multicenter, Placebo-Controlled, Double Blind, Randomized Trial Evaluating the Role of Oral Glutathione on Growth Parameters in Children with Cystic Fibrosis | | |
| Short Name | GROW - Glutathione in Young Children | | |
| Specimens Currently Available to Other Researchers | Not Yet | | |
| Current Study Status | Enrolling | | |
| Study Timeline Metrics | | | |
| | Planned | Actual (Sponsor) | |
| Begin Enrollment | 04/01/2017 | 07/05/2017 | |
| Complete Enrollment | 06/01/2018 | | |
| Study Complete | 12/01/2018 | | |
| Number of Patients Planned | 60 | | |
| General Study Information | | | |
| Study Type | Interventional | | |
| Intervention Type | Nutritional-GI Therapies | | |
| Study Drug (Primary) | Glutathione | | |
| Control Type | Placebo | | |
| Blinded | Yes | | |
| Randomized | Yes | | |
| Duration of Subject Participation | 6 Months | | |
| Endpoints Evaluated | Blood Inflammatory Mediators, Growth | | |
| Trial Specific Link on ClinicalTrials.gov | https://clinicaltrials.gov/ct2/show/NCT03020719?cond=cystic+fibrosis&intr=glutathione&rank=2 | | |
| Primary Manuscript Link | | | |
| Primary Manuscript Citation | | | |
| Eligibility Criteria | | | |
| Age | 24 Months to 10 Years | | |
| FEV1 | No FEV1 requirement | | |
| P. aeruginosa status | Not Applicable | | |
| B. cepacia status | Not Applicable | | |
| Other Primary Eligibility Requirements | Participants must have a weight-for-age between the 10th and 50th percentiles at screening. | | |
| Biorepository Specimen Information | | | |
| General Specimen Information | | | |
| 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 | |