Participating in a clinical trial provides an opportunity to help an individual when conventional treatment options are either not effective or not accessible. An individual's participation may provide immediate benefit and or may provide more effective treatments in the future for others with serious diseases. Your provider will determine on a case-by-case basis whether entering a clinical trial is in the best interest for you.

OPTIMIZE

The Cystic Fibrosis Research Team is currently enrolling participants in a nationwide clinical trial to treat early *Pseudomonas aeruginosa* Infection in Cystic Fibrosis. The purpose of the study is to compare different treatments to clear the *Pa* from your child's lungs and keep it away as long as possible.

CLINICAL STUDY DETAILS

Trial Summary
This is a multicenter, blinded, randomized, placebo-controlled clinical trial in children with CF ages 6 mos - 18 years with new onset *Pa*, defined as either a first lifetime documented *Pa* culture or a *Pa* positive culture after at least two years of negative cultures. The study will assess the clinical and microbiologic efficacy and safety of extended release azithromycin given every 14 days as an add-on therapy to culture-based tobramycin inhalation solution (TIS) among children with new onset *Pa*. Eligible participants will be randomized within one month of their *Pa* positive culture in a 1:1 fashion to receive one of the following two treatment strategies: (1) oral placebo given every 14 days for 18 months in addition to quarterly culture-based TIS therapy administered only in quarters for which children are *Pa* positive, or (2) extended release oral azithromycin given every 14 days for 18 months in addition to quarterly culture-based TIS therapy administered only in quarters for which children are *Pa* positive. Participants initiating TIS more than 14 days prior to the baseline visit for treatment of their *Pa* positive culture will be excluded.

Trial Funding
All participants may receive up to $477.00 for participation. Participants may also receive reimbursement for parking and mileage at the current federal business mileage rate should they apply.

Trial Eligibility
To be eligible, participants must meet the following inclusion criteria:

- Children with CF ≥ 6 months to ≤ 18 years of age
- Documented onset of positive oropharyngeal, sputum or lower respiratory tract culture for *Pa* within one month of the Baseline Visit, defined as: a) first lifetime documented *Pa* positive culture; or b) *Pa* recovered after at least a two-year history of *Pa* negative respiratory cultures (≥ 1 culture/ year)
- Clinically stable that doesn't require administration of IV anit-pseudomonal antibiotics, oxygen supplementation, and or hospitalization at the time of Baseline visit

Participants may not be eligible if any of the following exclusion criteria's are met:

- Weight <6.0 kg at the Baseline Visit

For a complete inclusion/exclusion criteria please contact the study team at cf.research@emory.edu

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REDOXY

The Cystic Fibrosis Research Team is currently enrolling non diabetic CF participant . The purpose of the study is to determine whether young children with CF have glucose-induced redox imbalance and to determine whether a meal with high glycemic index induces acute redox imbalance compared to a meal with a low glycemic index.

CLINICAL STUDY DETAILS

Trial Summary
This study has two AIMs and participants will be eligible for either aim but not both.

Aim 1
The first aim details two groups of subjects that will be evaluated: 27 CF children aged 2 to 8 years with a normal glucose tolerance (NGT) and 27 age-matched controls with NGT. An oral glucose tolerance test (OGTT) will be conducted for analysis. This portion of this trial is one visit only.

Aim 2
The second aim involves subjects that are 12 years and older with NGT. A meal challenge will randomize half of the participants to receive a test meal (milk shake) with a high glycemic index and the other half with a low index. Both the study staff and the subjects will be blinded and have no knowledge of who has taken the high glycemic or low glycemic meal.

Trial Funding
All participants may receive up to $40.00 for each visit.

Trial Eligibility
To be eligible for Aim 1, participants must meet the following inclusion criteria:

For CF children –

- CF diagnosed by pilocarpine electrophoresis sweat test and/or CFTR genetic mutation analysis;
- CFTR mutation analysis showing two Class I to III mutations;
- Aged 2 to 8 years
- On a clinically stable medical regimen for at least three weeks;
- No IV or oral antibiotics for a respiratory exacerbation for at least three weeks; and
- No hospitalization for at least six weeks.

For age-matched children (healthy) –

- No acute illness for at least six weeks;
- Never been hospitalized except at birth following a full term delivery;
- Aged 2 to 8 years; and
- Without any chronic illness requiring prescription medications.

Participants may not be eligible Aim 1 if any of the following exclusion criteria's are met:

For CF children –

- Current or past diagnosis of CFRD; or
- Parents unwilling to have an IV inserted for blood draws.

For healthy children –

- Parents unwilling to have an IV inserted for blood draws.

To be eligible for Aim 2, participants must meet the following inclusion criteria:

- CF diagnosed by pilocarpine electrophoresis sweat test and/or CFTR genetic mutation analysis
- CFTR mutation analysis showing two Class I to III mutations;
- Aged 12 years or older;
- On a clinically stable medical regimen for at least three weeks; and
- No IV or oral antibiotics for a respiratory exacerbation for at least three weeks.

Participants may not be eligible Aim 2 if any of the following exclusion criteria's are met:

- Current or past diagnosis of CFRD; or
- Allergy or intolerance to egg or dairy products

For a complete inclusion/exclusion criteria please contact the study team at cf.research@emory.edu

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PREVENT

The Cystic Fibrosis Research Team is currently enrolling participants with Cystic Fibrosis that may be at high risk for diabetes.

CLINICAL STUDY DETAILS

Trial Summary

A randomized, double-blind, placebo-controlled study to determine whether chronic treatment of cystic fibrosis subjects with impaired glucose tolerance using Sitagliptin (Januvia^{tm}) prevents the development of diabetes. This is a daily oral dose with 7 study visits over the course of 15 months.

Trial Funding
You will be paid $50 for study visits #1 and Repeat OGTT for Confirmation of CFRD visit if needed. You will be paid $100 for each study visit for study visits #2, 4, & 6. You will be paid $25 for each study visit for study visits #3 & 5. If you do not finish the study, you will be paid for the visits you have completed. Compensation for study visits will be provided as check or gift card depending on your enrollment location.

Trial Eligibility
To be eligible, participants must meet the following inclusion criteria:

- Aged 13 years of age or older at the time of enrollment.
- Clinically stable with no lower respiratory tract exacerbation requiring intravenous antibiotics in the three weeks prior to enrollment.
- On a stable clinical treatment regimen for at least three weeks prior to enrollment.
- High risk prediabetes found on an OGTT performed at screening 8 weeks or less before enrollment.

Participants may not be eligible if any of the following exclusion criteria's are met:

- Diagnosis of CFRD.
- Taking chronic systemic glucocorticosteroids during the past month.
- On insulin therapy during the past month.
- CF lung disease severe enough to require daytime chronic oxygen therapy via nasal cannula during the past month
- Pancreatic sufficient

For a complete inclusion/exclusion criteria please contact the study team at cf.research@emory.edu

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QBW251

The Cystic Fibrosis Research Team is currently enrolling participants with Cystic Fibrosis

CLINICAL STUDY DETAILS

Trial Summary
This is a randomized, double blind placebo-controlled study to assess the safety, tolerability, pharmacokinetics, and preliminary pharmacodynamics of single and multiple ascending doses of QBW251 in healthy subjects and multiple doses in cystic fibrosis patients.

Trial Funding
Subjects have the potential to be compensated $600 for their participation in the study.

Trial Eligibility

To be eligible, participants must meet the following inclusion criteria:

- Male and female participants 18 to 55 years of age
- A documented CFTR genotype defined as a class III, IV, V, or VI mutation on one allele **and** on the other allele any other CFTR mutation with the exception of F508del/F508del due to its designation as either a class II or III mutation.
- FEV1 at Screening must be 50 to 90% predicted

For a complete inclusion/exclusion criteria please contact the study team at cf.research@emory.edu

Studies are constantly updating so please check back with us often!!