Streamlined Treatment of Pulmonary Exacerbations in Pediatrics

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 years to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Age
    1. For main cohort and non-HEMT cohort: age 6 to <19 years
    2. For preschool cohort: age 3 to <6 years
2. Documentation of a CF diagnosis as evidenced by one or more clinical features consistent with the CF phenotype and one or more of the following criteria:
    1. sweat chloride ≥ 60 mEq/liter
    2. two disease-causing variants in the cystic fibrosis transmembrane conductive regulator (CFTR) gene
3. Written informed consent (and assent when applicable) obtained from participant or participant's legal representative and ability of participant to comply with the requirements of the study
4. Highly Effective Modulator Therapy
    1. For main cohort and preschool cohort: Taking HEMT for at least 3 months at enrollment
    2. For non-HEMT cohort: not eligible for HEMT based on CFTR genotype or eligible but not taking for at least 3 months and no plans to start HEMT in the next year, and also not taking tezacaftor-ivacaftor or lumacaftor-ivacaftor for at least 3 months
5. For main cohort and non-HEMT cohort: able to perform acceptable and reproducible spirometry
6. For main cohort and non-HEMT cohort: ppFEV1 ≥ 50% predicted at enrollment based on the Global lung Initiative (GLI) reference equations
7. Ability to receive text messages and access the internet

Exclusion Criteria:

1. Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the individual or the quality of the data
2. Receiving an acute course of oral or IV antibiotics at the time of enrollment or within the 14 days prior to enrollment. Individuals may be re-screened ≥21 days after completion of antibiotics if they are at their baseline state of health, per self-report
3. Treatment with systemic corticosteroids at enrollment or within the 14 days prior to enrollment. Individuals may be re- screened ≥21 days after completion of systemic corticosteroids if they are at their clinical baseline, per self-report
4. History of solid organ transplant
5. History of positive culture for Mycobacterium abscessus in the 12 months prior to enrollment
6. Treatment with antibiotics for any non-tuberculous mycobacteria (NTM) at enrollment
7. Three or more IV antibiotic-treated PEx in the 12 months prior to enrollment
8. Treatment with chronic oral antibiotics other than azithromycin at enrollment
9. Treatment with systemic corticosteroids for allergic bronchopulmonary aspergillosis (ABPA) in the 12 months prior to enrollment

Conditions & Interventions

Interventions:
OTHER: Immediate Oral Antibiotics, OTHER: Tailored Treatment: Oral Antibiotics only if Additional Treatment needed
Conditions:
Cystic Fibrosis
Keywords:
cystic fibrosis, oral antibiotics, pulmonary exacerbation, pediatric

More Information

Description:
The STOP PEDS RCT is a multicenter, parallel, open label randomized controlled trial evaluating the long-term (one year) and short-term safety and efficacy of two antibiotic treatment strategies for the management of outpatient pulmonary exacerbations (PEx) in the pediatric CF population.

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Phase: NA
IRB Number:
System ID: NCT06654752

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